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Biological Control Quarantine: Needs and Procedures

Proceedings of a Workshop

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Preface

The ARS Workshop, Biological Control Quarantine: Needs and Procedures, held in January 1991 in Baltimore, had the following five objectives:

- To assess biological control quarantine capability in the United States.
- To determine strategic deployment of new quarantine or containment facilities, if needed.
- To develop a communications network and coordination system for biological control quarantine activities.
- To assess the adequacy of taxonomic support (research and identification services) for biological control quarantine activities.
- To review the adequacy of quarantine facility design, quarantine operational procedures, and regulations affecting biological control quarantine activities.

The Workshop was developed under the leadership of Dr. Richard S. Soper, ARS National Program Leader for Biological Control, who chaired a Workshop Steering Committee consisting of W. L. Bruckart, J. R. Coulson, and R. W. Fuester (ARS); F. D. Bennett (University of Florida); G. Gordh and T. W. Fisher (University of California, Riverside); J. R. Cate (USDA-CSRS); N. C. Leppla (USDA-APHIS); and W. W. Metterhouse (New Jersey Department of Agriculture). Thanks for a successful Workshop must go to the invited speakers and to over 120 participants. Other key ARS personnel heavily involved in the Workshop were M. M. Athanas and S. D. Hight, Local Arrangement Chairs, who, with personnel from the Baltimore-Washington International Airport Comfort Inn, made the Workshop an organizational success; R. W. Fuester and J. R. Coulson, Publicity/Communications Chair and Publication/Report Chair, respectively; and above all, the six Working Session Chairs, R. W. Fuester, W. R. Nickle, P. C. Quimby, Jr., R. A. Humber, W. L. Bruckart, and G. C. Papavizas, whose participation prior to, during and subsequent to the Workshop was critical. Funds for travel of some of the Workshop participants were provided by the APHIS National Biological Control Institute (NBCI), which is hereby acknowledged with thanks.

A critique of the ARS Workshop was published in April 1991 by Agriculture Canada (A. Schmidt and M. Sarazin, 1991. Report on U.S.D.A. Workshop on Biological Control Quarantine: Needs and Procedures, Agric. Canada, Res. Branch, Biocontrol News 4: 1-7). The ARS Workshop was followed by a closely-related USDA-CSRS

Workshop on Guidelines and Regulations: Critical Issues in Biological Control, held in Vienna, Virginia, June 10-12, the Proceedings of which are soon to be published.

These Proceedings have been prepared by J. R. Coulson, R. S. Soper, and D. W. Williams. It is for the readers of these Proceedings to determine how well the objectives of the ARS Workshop were met, much of which will depend on future actions resulting from recommendations made by the Workshop.

Acronyms used in Text

APHIS	Animal and Plant Health Inspection Service (USDA)
ARS	Agricultural Research Service (USDA)
BATS	Biological Assessment and Taxonomic Support (PPQ)
BBEP	Biologics, Biotechnology, and Environmental Protection (APHIS)
BCDC	Biological Control Documentation Center (ARS)
BL	Biosafety Level
CDC	Centers for Disease Control
CSRS	Cooperative State Research Service (USDA)
EA	Environmental Assessment
EIS	Environmental Impact Statement
EPA	Environmental Protection Agency
EUP	Experimental Use Permit
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
IOBC	International Organization of Biological Control
MPCA	Microbial Pest Control Agent
NBCI	National Biological Control Institute (APHIS)
NEPA	National Environmental Policy Act
PPQ	Plant Protection and Quarantine (APHIS)
ROBO	Releases of Beneficial Organisms Data base
SEL	Systematic Entomology Laboratory (ARS)
TAG	Technical Advisory Group for the Introduction of Biological Control Agents of Weeds
USDA	United States Department of Agriculture
VS	Veterinary Services (APHIS)

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Final drafts resulting from reviews of early drafts by scientists at and subsequent to the Workshop

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Executive Summary

The demand for biological control of pests using their natural enemies is increasing as agriculture in the United States moves toward ecologically benign methods of pest control. Classical biological control, which has enjoyed great success historically, involves the importation of predators, parasitoids/parasites, pathogens, antagonists, and weed-feeding organisms to control exotic pests that have entered the country without natural enemies. The application of classical biological control depends upon the movement of beneficial organisms into the U.S., and hence, upon the existence of safe and efficient quarantine facilities and procedures.

Containment or quarantine of beneficial organisms is necessary to assure both the continued success of biological control and the safety of U.S. agriculture and environment. Effective quarantine screening assures that natural enemies released into the environment for pest control will be free of their own natural enemies and diseases. Host range testing in quarantine is crucial to prevent the release of candidate beneficial species, such as weed-feeding insects, which might become pests themselves.

The objective of this workshop was to examine the current status and needs of biological control quarantine. The participants (listed in Appendix 1) included representatives from federal and state regulatory agencies, quarantine facilities, the research community, and industry. Position papers were presented during the first two days of the workshop. Topics included viewpoints from regulatory agencies, action agencies, researchers, and industry. They presented current needs and reviews of all aspects of quarantine procedure from importation of an organism through its field release. On the third day, the participants were divided into six groups for intensive discussion of needs and procedures. The groups were delineated by natural enemy taxa: arthropod natural enemies of arthropod pests, arthropod-parasitic nematodes, invertebrate weed feeders, arthropod pathogens, weed pathogens, and natural enemies and antagonists of plant pathogens and nematodes. In addition to needs, the groups discussed the proposed guidelines for importation, interstate movement, and release of exotic organisms, which are included as Appendix 3 to these Proceedings. Appendix 2 is a paper that discusses issues important to the safe release of exotic natural enemies of weeds in North America.

The present status of biological control quarantine was assessed by responses to a questionnaire mailed out

before the workshop (q.v., Chapter III of the Proceedings). Currently, there are 22 existing facilities and nine planned. They are primarily devoted to arthropod parasites and predators and weed-feeding arthropods. Most facilities are at or near their full capacity.

Several important resource needs were identified. A general commitment to maintaining and upgrading existing facilities is critical. In addition, several additional facilities are needed to meet regional demands. In the realm of taxonomy, needs include increased support for research on taxa relevant to biological control, an increase in taxonomic services, and a system of repositories for voucher specimens.

Many procedural needs surfaced during the workshop. The clearance of beneficial organisms through ports of entry must be expedited. Quarantine officers must be trained uniformly, and standard operating procedures must be established for all facilities. The requirements of regulatory agencies, and the laws they enforce, must be clarified and should be open to input from the scientific community. Finally, documentation and communication of biological control activities must receive greater support.

In addition to the major Workshop recommendations listed in Chapter I, many other more specific problems and needs were identified and recommendations made. These can be found in both the position papers (Chapter II) and Working Session reports (Chapter IV).

An important part of these Proceedings is the proposed ARS procedural "guidelines" for the continued safe and legal conduct of classical biological control research by ARS. Separate guidelines were presented for six different groups of biological control organisms (Appendix 3). As indicated in Appendix 3, questions and unresolved problems were identified, many of which require resolution by discussions with pertinent regulatory agencies or by additional scientific panels. Many proposals and recommendations have been made to address these issues. The guidelines will remain in draft until these problems are resolved. Additional comments on the Guidelines are solicited. Even when "final" documents are prepared and accepted by ARS administration, it is expected that the Guidelines will remain dynamic documents, to be updated as new research results become available and regulatory procedures change.

Chapter I. Workshop Recommendations

General Resource Needs¹

Facility Needs

- Many facilities are aging. There needs to be a commitment to and support for maintaining and upgrading these facilities.
- Additional regional quarantine facilities are needed for invertebrate biological control agents in the northwestern and north central United States and in the Caribbean region.
- A facility should be established for exotic organisms for the control of subtropical weed species in central or southern Florida.
- Development of weed pathogens should be expedited by constructing additional containment facilities and staffing them with trained personnel (technical as well as scientific). Potential locations are Bozeman, Montana; Fayetteville, Arkansas; and Albany, California.
- A facility is needed in Montpellier, France, to expedite the testing of biological control agents from Eurasian countries outside the European Economic Community.

Coordination/Communication Needs

- The National Biological Control Institute (NBCI) recently established by the Animal and Plant Health Inspection Service (APHIS) should be encouraged to develop an electronic bulletin board for the exchange of information on biological control.

General Taxonomic Research and Service Needs

- Additional systematic capabilities are needed in several significant groups of insects, plants, and phytopathogenic fungi. These needs are primarily for morphological taxonomy, as opposed to molecular biological applications.

- Costs for taxonomic services should be built into biological control project budgets. Systematists should be involved in a project from its start. In addition, there are needs for increased support personnel for diagnostic services covering all groups of potential control agents.
- Lists of taxonomic specialists to provide identification services for biological control targets and agents should be accessible on an electronic bulletin board.
- A system of long-term repositories for the suitable deposition of biological control voucher specimens should be developed.

General Procedural Needs²

Importation considerations

- Means should be explored with quarantine and customs service personnel to expedite the clearance of materials through ports of entry.
- An auxiliary label for shipments of biological control agents should be developed to indicate the beneficial contents of the package.

Specific facility needs; levels of containment

- APHIS certification of biological control microbiology facilities should allow blanket permits for defined groups of microbes for importation and interstate movement between approved containment facilities.

Quarantine Officer: duties and training

- Training procedures for containment and quarantine officers should be developed.
- Periodic workshops for officers should be held to review quarantine needs, coordination, and communication.

Quarantine receipt, handling, testing, and storage procedures

- All biological control facilities should develop standard operating procedures.
- A uniform policy is needed for the elimination of mites, microbial pathogens, and nematodes from beneficial arthropods.
- In general, host range testing and culturing of weed control agents should be done in overseas facilities, but flexibility should be allowed to conduct testing in quarantine on a case-by-case basis. If sufficient testing cannot be done in an overseas facility, approval should be obtainable from the Technical Advisory Group for the Introduction of Biological Control Agents of Weeds (TAG) for such quarantine testing.

Documentation

- Documentation of the releases of beneficial organisms (ROBO) should be made more user friendly for input of and access to data.
- Preservation of voucher specimens should be encouraged for all biological control agents brought through quarantine. (See also the fourth recommendation under General Taxonomic Needs above.)

¹ See also specific recommendations in the following chapters.

² See also specific recommendations in the following chapters and in Appendix 3.

Specific taxonomic research and service needs

- Increased diagnostic services for insect pathogens are needed in support of quarantine operations.

Considerations for release from quarantine

- Requirements under the National Environmental Policy Act (NEPA) need to be clarified.
- Efforts should be made to assure that APHIS recommendations on regulations receive input from scientists outside the agency prior to the publication of the recommendations in the Federal Register.
- The TAG should be kept in its present configuration with the addition of expertise in plant pathology. The chairman of the TAG should continue to use and emphasize the use of specialized scientific expertise in providing information for decisions. The concept of public notification of action by APHIS Plant Protection and Quarantine (PPQ) on TAG recommendations with regard to candidate target weeds should be approved.

Chapter II. Abstracts of Workshop Papers and Discussions

Introductory Session

Regulatory Agency Viewpoints

Federal Viewpoint *J. H. Payne*, Microbiologist, Biotechnology Coordination and Technical Assistance; Biologics, Biotechnology, and Environmental Protection (BBEP), APHIS, Hyattsville, Maryland.

Abstract not received.

Federal Viewpoint *E. M. Imai*, Senior Operations Officer, Biological Assessment and Taxonomic Support (BATS), PPQ, APHIS, Hyattsville, Maryland.

The Plant Quarantine Act of 1912 provides APHIS the authority to regulate the movement of plants and plant products from foreign and off-shore U.S. locations into the continental United States, including Alaska. The purpose of quarantines and regulations is to prevent the introduction of pests not known to occur in or not widely distributed in the U.S. and known to be on or in foreign plants and plant products. Quarantines and regulations promulgated under the Plant Quarantine Act allow entry of plants and their products when no pests are found and deny entry or require treatment if pests are found.

The Plant Quarantine Act may be applied only indirectly to cases in which someone wants to import a pathogen or an arthropod of quarantine significance into the U.S. without its host. To cover such cases directly, the Federal Plant Pest Act was passed in 1957 and has been enforced by APHIS PPQ. PPQ is charged with the responsibility to prevent the dissemination of plant pests into or within the U.S. and its Territories by regulating their movement. PPQ employs procedures to carry out this charge while minimizing impediments to foreign commerce and travel. The same policy is applied to interstate commerce and travel.

The Deputy Administrator of PPQ has delegated enforcement of the federal plant pest regulations to the BATS Permit Unit. Any resident who wishes to move plant pests into or through the U.S. may apply for a permit to authorize such movement. The resident sends the permit

application to the appropriate state regulatory official. The state official then sends the application to the BATS Permit Unit, which conducts a biological assessment, including the risk of dissemination, containment of the pest, and eradication possibilities in the event of escape. State regulatory officials are involved in the permit decision through Part 33.22 of the Act, which provides a mechanism to consult others on the potential risks of plant pest dissemination associated with its movement into the U.S. or interstate. State regulatory officials are always contacted for their opinions.

From the viewpoint of PPQ, plant pests represent a high risk for dissemination and are to be regulated according to provisions of the Federal Plant Pest Act. The Act has provisions for assessing risk through Part 33.21. The Act also has various safeguarding requirements, including Part 33.21 (a) (12), which requests information on "measures to be employed to prevent danger of plant pest dissemination," Part 33.21 (a) (11), which requests information on "intended use," Part 330.201 (a) (7), which requests information on "method of shipment," and Part 33.22 (b), which delegates the authority to "...inspect the site where the plant pests are proposed to be handled...to determine whether existing or proposed facilities will be adequate to prevent plant pest dissemination in case a permit is issued..."

State Viewpoint *H. A. Denmark*, Chief, Bureau of Entomology, Division of Plant Industry, Florida Department of Agriculture and Consumer Services, Gainesville, Florida.

The United States did not enact a quarantine law until 1912. Florida passed the Florida Plant Act in 1915 following the find of citrus canker. Florida continued port inspections in 1958 when the responsibility was turned over to APHIS PPQ. Florida now has an Arthropod and Arthropod Pathogen Introduction Committee to screen and make recommendations of the movement of all arthropods into Florida.

Biological Control Research Viewpoints

Quarantine “Philosophy”: Perspectives and Constraints of Biocontrol Research from a Federal Viewpoint

R. W. Fuester, Research Leader, Beneficial Insects Research Laboratory, Agricultural Research Service (ARS), Newark, Delaware.

Three agencies of the United States Department of Agriculture (USDA) operate or share in the operation of about half of the nation's 23 biological control quarantine facilities: ARS, APHIS, and the USDA Forest Service. In all three agencies, federal biological control quarantine facilities are primarily involved in classical biological control of insects, weeds, and other pests, where they serve as a vital link between foreign exploration for and domestic colonization of exotic natural enemies. The greatest emphasis on biocontrol research is in ARS, where about 70% of the incoming shipments of exotic organisms are for research purposes.

Federal biocontrol research is focused on high priority national pest problems, so only limited resources can be devoted to courtesy pass-through operations in support of research or action programs in progress at universities and state agencies. This problem has become even more critical with the recent loss of personnel at some federal locations. Most facilities are fairly new but some require upgrading. Space seems to be a limiting factor at several locations. Most directors of federal biocontrol quarantine facilities report funding as a major problem. Some facilities appear to be under-utilized, but others have very high volume operations, and some adjustments in routing of incoming shipments appear necessary.

Because it is of paramount importance that we know just what organisms we are dealing with, a major concern is the overall lack of support for systematics, not only because many groups cannot be identified to species, but as an emerging trend with new scientists being drawn from training for careers in taxonomy to biotechnology. Another disturbing trend appears to be a potential for greatly increased complexity in the approval process for release of candidate natural enemies from quarantine with what many fear will involve excessive and, in some cases, unnecessary host range testing. Lesser concerns involve dealing with unsolicited shipments, clearing shipments at ports of entry, increasing numbers of requests to conduct

research on pest insects in quarantine, and serving the increasing needs of a growing biological control community.

University Perspectives and Quarantine-Related Constraints on Biological Control Research

T. W. Fisher and R. D. Goeden, Quarantine Officer and Professor, Department of Entomology, University of California, Riverside, California.

Historically, university researchers have contributed significantly to the development and use of biological control in the United States. For example, the University of California has been involved in the quarantine processing of imported beneficial arthropods since 1923, then under the leadership of Harry S. Smith, who coined the term “biological control”. Early biological control work in this country was a highly personalized venture among like-minded, hard-working, creative and highly capable individualists who worked together on a first name basis and developed strong personal and professional bonds that transcended federal and state agency affiliations. However, the day of individual pursuit of biological control research has largely passed, as funding and public support for biological control continues to grow and attract agencies, researchers, and practitioners with different backgrounds, capabilities, and agenda. This growth and increased recognition and use of biological control follows years of widespread organic pesticide abuse and attendant problems with insecticide resistance, the beginnings of herbicide resistance, and a greatly enhanced, public ecological awareness and increasingly voiced, widespread concern for the environment.

Regulatory constraints on biological control are currently viewed from a university perspective as that of regulated, active practitioners, who, unfortunately, may be destined to become mere bystanders and teacher/chroniclers of federal and non-university state research efforts, if regulations governing this field become too restrictive and oppressive. One constraint, especially noticeable in recent years, is the diminished support for taxonomy, manifested primarily as the inability to obtain prompt identifications of parasitic, predaceous, and phytophagous arthropods. The glamour of, clamor for, and support of high-cost, high-technology research, funded in entomology at the

expense of traditional research in taxonomy, systematics, anatomy, and morphology is apparent to all but the most naive or rabid adherents of molecular biology.

We strongly recommend that USDA APHIS be legally empowered to regulate the importation of beneficial organisms separately and as distinct from arthropod pests. Separate authorization would allow the issuance of special labels to identify shipments containing beneficial arthropod parasites, predators, and phytophages. It would also allow trained APHIS inspectors to recognize and speedily process these shipments for consignment to a quarantine laboratory. Sufficient flexibility should also be introduced into the wording and conditions stated on shipping permits to allow the discretion needed by collector, inspectors, and quarantine handlers to facilitate the rapid movement of imported natural enemies.

Biological Control Action Agency Viewpoints

Federal Viewpoint *D. E. Meyerdirk*, Chief Operations Officer, Biological Control Operations, PPQ, APHIS, Hyattsville, Maryland.

Pest control through chemical means has come under increased scrutiny in recent years because of new environmental concerns. These concerns center on ground and surface water contamination, human safety and health, and pesticide misuse. Biological control has recently moved to the forefront as a viable pest control option. APHIS has developed Biological Control Operations, whose goal is to implement biological control programs in order to control agricultural pests of economic importance in a cooperative effort with federal and state agencies. The principal objective is to utilize biological control technology taking actions which maximize the use of natural enemies and involve importation, screening, rearing, release, redistribution, and evaluation within each program. Funding within APHIS to support biological control programs has increased from \$1.6 million in 1980 to \$7.2 million in 1991. Projects have increased during that time from one program targeting the alfalfa weevil in 1980 to eight additional projects, including Colorado potato beetle, European corn borer, Russian wheat aphid, sweetpotato whitefly, euonymus scale, grasshoppers, leafy spurge, and diffuse and spotted knapweeds.

The need for federal involvement in implementing biological control programs is significantly increasing. The first order of business is to maintain a safe protocol for the introduction and release of all biological control agents. This must be followed by the development of an expeditious program that is sensitive to the international concerns of countries north and south of the United States. Programs will be limited by the availability of resources, including funds, facilities, and labor, which will mandate the number of projects and intensity of the programs. The need for taxonomic services and quarantine facilities could create a logjam. Quarantine facilities will be needed not only for research screening of exotic species of natural enemies, but also for the quick screening of biological control agents formally approved for release (as in the case of biological control agents for weeds). A quarantine matrix which cross links quarantine facilities and shares the workload on national biological control projects can help alleviate any immediate needs. This has been accomplished with the existing Russian wheat aphid program. Future success will depend on the continued cooperation of federal and state agencies in effectively and efficiently sharing existing resources.

Biological Control Programs from a State Perspective *W. W. Metterhouse*, Director, Division of Plant Industry, New Jersey Department of Agriculture, Trenton, New Jersey

With the increasing emphasis in finding alternatives to chemical pesticides, the states are increasing their efforts in biological control. There are a number of states seeking funding to construct new biological control laboratories. Certainly there will be greater efforts in the future in the importation from foreign countries and domestic movement of biological materials.

This should not lead one to believe that these are new efforts by the states, however. For example, the New Jersey Department of Agriculture has a long history in the use of biological controls in both classical and augmentation practices. Our first efforts began with the control of the Japanese beetle. After the introduction of the beetle into Riverton, New Jersey, in 1917, efforts were initiated cooperatively with ARS and the Rockefeller Institute in 1923. At that time, there was a laboratory-produced and field-distributed nematode, *Neoaplectana glaseri*, and the milky spore disease, *Bacillus popilliae*. Following that

effort, biological control efforts were conducted against oriental fruit moth, European corn borer and sawflies, both the introduced European pine and native sawflies. The production and release of a sawfly pupal parasite, *Dahlbominus fuscipennis*, was instrumental in reducing sawfly population levels.

In more recent times, a most successful effort was the cooperative program with ARS in the release of parasites for the control of the alfalfa weevil. In 1959, field insectaries were established in which parasites were cultured, collected and distributed to other areas of the state. This program alone is saving growers hundreds of thousands of dollar each year in pesticides.

In 1963, the Department embarked on a large parasite rearing and release program against the gypsy moth. In fact, New Jersey was the first state to mass produce gypsy moth parasites. In 1971-78, the Department established a cooperative agreement with APHIS for the purpose of developing mass rearing techniques, production, and distribution of parasites to the states and research institutions. During this period of time, 27 species of gypsy moth parasites were reared and shipped to 16 states.

Presently the Department is involved in ten biological control programs. Of these programs, that having the highest priority is the control of Colorado potato beetle on eggplant utilizing *Edovum putterli*. This program has been demonstrated to save as much as ten applications of pesticides. Another significant program that is being developed is the use of predaceous mites in fruit orchards, vegetable and ornamental plants. Still others are the use of biological agents in the control of euonymus scale, Canada thistle, velvet leaf, and asparagus beetle.

I should point out that in 1985 we constructed a new 21,000 sq. ft. beneficial insect rearing laboratory consisting of administrative offices, service areas, rearing rooms and a special quarantine area. We have since added three greenhouses, and storage buildings. At the present time, there are 20 staff members devoted to the biological control programs. In addition to the main rearing facility, we have two field laboratories located in the northern and southern areas of the state.

What is the role of State Departments of Agriculture? Certainly not to carry out research but to transfer those new biological control technologies into production and

release for implementation purposes. APHIS plays an important role in cooperating with the states in the implementation of control programs.

One such successful cooperative program, and the first large-scale implementation effort, was the cereal leaf beetle parasite program.

Another example is the Mexican bean beetle parasite program. ARS imported and studied the parasite, *Pediobius foveolatus*. APHIS, through a regional pilot project, demonstrated that the parasite could be used in a successful release program. Those technologies were transferred to the states for implementation. This program is employed in New Jersey and other states on an annual basis. The program is saving millions of dollars in pesticide use by growers of soybeans.

Although the states have played and will continue to play an important role in the implementation of biological programs, I do want to emphasize that I strongly support and encourage private enterprise to develop rearing facilities and to market biological control agents. The role of government should be to provide for adequate research and development of new alternative methods of insect and plant disease control. Once these technologies are developed, industry should be encouraged to prepare for production, marketing and field services necessary to the implementation of these biorationals. Certainly in the future, with a greater involvement of private pest management consultants and a production industry, there exists a need for some regulation.

To protect the consumer or user of beneficial insects or other organisms, such material when produced should maintain its biological integrity. Production protocols should be established to protect biological integrity as necessary to maintain its effectiveness. All parasites, predators, or other organisms should be properly labeled as to use and be supported by efficacy data.

Let me provide an example of misrepresentation of a parasite and flagrant marketing practices. Several years ago, a town in New Jersey, with good intentions, purchased *Trichogramma* spp. for control of gypsy moth. Obviously, this genus of parasite does not attack the gypsy moth. Even more embarrassing, this problem was brought to my attention by a state legislator. This kind of marketing practice does little to provide credibility to biological

control and only supports the need to develop protocols and guidelines in a legal framework that are workable.

Apart from my role as an administrator of biological control programs, I am also a regulatory official. I am concerned about the foreign importation of exotic materials. Importations are being made by private or commercial interests. All that is required by APHIS is an import permit with no screening protocols. This represents a risk to the U.S. in the introduction of a foreign pest, plant disease, or hyperparasite. What assurances do we have that these materials are being handled in a scientific manner?

Let me provide an example of what comes through our ports. This past year, I was notified by the Agricultural Quarantine Inspectors at Port Elizabeth, New Jersey, that they intercepted a shipment of beneficial insects (i.e., whitefly parasites). These insects were imported by a New Jersey broker dealing in plants and seeds. Upon notification, I requested that the shipment be sent to the ARS Beneficial Insect Laboratory in Newark, Delaware, where the material would be identified and screened before delivery to the importer.

Domestic movement of biological control agents represents another regulatory concern. At the present time, private rearing companies are shipping beneficial agents interstate. They do on occasion complete an APHIS 526 application. This is an application for the purpose of moving plant pests interstate. All 526 applications must be reviewed and approved by the state of destination. The movement of common beneficial insects does not require the completion of a 526 application. Certainly, the domestic movement of biological materials can represent a risk in the introduction of biological contamination or accelerate the spread of a pest within the U.S.

I am not a supporter of more cumbersome regulations. We may also perceive the risk in the movement of biological materials as being low. I believe, however, that we must get our act together by establishing protocols and guidelines that provide for regulatory uniformity. I believe it is important that we as specialists in the field of biological control have input and take the first steps in establishing these guidelines. Any proposed regulations must be reasonable and workable. Certainly, we do want to

encourage research and development in biological controls and to promote private enterprise in the production and distribution of biorationals to the consuming public.

Industry Viewpoint

A View from Industry *J. W. Smith*, Senior Entomologist, Insect and Nematode Research, Rhone-Poulenc Agricultural Company, Research Triangle Park, North Carolina.

Rhone-Poulenc is committed to the idea that a worldwide test center for insecticides is necessary for maximizing research and development efficiency in creating and developing new insecticidal compounds. Rhone-Poulenc has chosen the Research Triangle Park, North Carolina, as this center. To fully develop its potential, the site at Research Triangle Park needs to have the capability to perform any sort of insecticide testing possible.

To help promote the Research Triangle Park site, the Biology group has proposed, and Rhone-Poulenc management has approved, a high risk insect containment facility to be located there. In concept, its purpose will be somewhat different than that traditionally associated with a quarantine facility. Rhone-Poulenc proposes rearing a variety of plant pests, either market-driven exotics, or strains of common species highly resistant to commercial insecticides.

Rhone-Poulenc has proposed a five-year plan, which will allow the building, testing, and commercial use of a quarantine facility to house the pest cultures. Exotic pests include *Heliothis armigera*, *Spodoptera littoralis*, *Nilaparvata lugens*, and *Polyphagotarsonemus latus*. Common species with high insecticide resistance from elsewhere in the world include *Plutella xylostella* from Malaysia and *Heliothis zea* from Colombia.

Rhone-Poulenc feels that it is imperative to develop the Research Triangle Park site for the purposes of model development, studies of market exotics, and resistance monitoring. The alternative, studying a particular population in its home range, has proven ineffective and unreliable.

Overview and Discussion

A Common or Unified Quarantine Perspective

N. C. Leppla, Director, Plant Methods Development, Science and Technology, APHIS, Hyattsville, Maryland.

Valuable facilities for screening exotic biological control agents under quarantine could be lost in this time of austerity and cutbacks, if they are not organized into an interdependent system with acceptable standards and protocols. These quarantine facilities currently range from a rebuilt prison warden's house in North Carolina to the modern units at Frederick, Maryland; Newark, Delaware; and Annapolis, Maryland. The pertinent questions are what is an appropriate structure for a comprehensive system, how should it function and be coordinated, how can it be developed and deployed, and who pays and who benefits?

A suitable biological quarantine system can be designed only after another series of questions is answered. What procedures should be standardized? What kinds of expertise are required and how do we assure that it is available? Is biological control adequately interfaced with integrated pest management? How can better delivery systems for biological control be fostered? Should some form of self-regulation be considered? How should biological control successes be documented and publicized? Can and should biological control become less esoteric?

Elements to be considered in a comprehensive quarantine system are as follows:

- Foreign Exploration/Collection--Identification of collecting, systematics, and rearing expertise; and the handling and transportation of viable specimens.
- Importation and Quarantine--Security, Permitting, Screening, Holding, Rearing, and Research. How much research is warranted before release? Can inadvertent selection be avoided or intentional selection be accomplished during rearing? Who owns the material and who should have access to it? How is the availability of organisms communicated?
- Release--Limited release in greenhouses or isolated field plots and unconditional field release (implementation). How is expediency encouraged without jeopardizing safety? Can both honest and dishonest mistakes be

prevented? Is it possible to avoid damaging the credibility of biological control?

- Establishment/Augmentation/Conservation--Goals for establishment and recolonization, commercial product development, and preservation of accomplishments.
- Evaluation--Biological, economic, and political evaluations require appropriate sampling methods, documentation, voucher specimens, systematics support, economic analysis, and enabling legislation. Periodic reevaluation is also necessary.

Protocols are required to coordinate the system and assure its success. Are uniform, generic procedures and standards possible? How would they be documented and enforced? Who would provide training and certification for personnel and what is required? How much standardization is warranted? Zealous action is needed, but claims and expectations must be conservative as the frequency of establishment/efficacy of biological control agents is increased.

The following three categories indicate who pays and who benefits:

- Taxpayer/Consumer--Pays for governmental activities that increase the availability of agricultural products and eliminate potential environmental hazards.
- Producer/Distributor--Pays for pest control that is more persistent and therefore cost effective.
- Scientist/Practitioner--Pays opportunity costs of career public service and enjoys the many benefits.

It is time to commit the resources needed to improving agriculture and the environment through advancements in biological control. It is a long-term pest control strategy, with relatively high initial costs when compared with systems based on annual profits. Moreover, it requires more sophistication in delivery. Thus, the costs and benefits of biological control must be amortized over many production seasons. This workshop is an important step in dealing with the complexity of issues involved in developing a supportive biological control quarantine system within the integrated pest management realm that it supports.

Session I: Quarantine Needs

Existing and Planned Quarantine Facilities

E. M. Imai, Senior Operations Officer, BATS, PPQ, APHIS, Hyattsville, Maryland.

The locations of existing and planned quarantine facilities in the United States according to PPQ records are shown in the following list.

The process of approving a new quarantine entails responsibilities by both the facility director and APHIS PPQ. A facility director first files a notification of intent

to PPQ. The closest PPQ field office is selected to monitor progress of the new facility. The facility director then submits a proposal to PPQ, followed by construction plans and blueprints. PPQ may require on-site reviews and evaluations to ensure compliance with its requirements. PPQ has the responsibility of reviewing the notification of intent and making recommendations, if needed. PPQ selects a field representative who monitors progress and reports to headquarters staff. The field representative takes the lead in the project with headquarters staff serving in an advisory role. He conducts site evaluations, if needed, and tracks completion of any changes or modifications to the original plans.

List of existing and planned quarantine facilities in the United States and its territories according to PPQ records, January 1991. (*Editors' Note:* This list has been prepared from that provided by Mr. Imai. As a result of a survey conducted in conjunction with this workshop, updated information on U.S. biological control quarantine facilities has been prepared (q.v., Chapter III and Tables 1-5 therein).)

Laboratory	Target and/or Natural Enemy Organisms	Responsible Individual(s)
Facilities Maintained by the U.S. Department of Agriculture		
USDA-ARS Beltsville, MD 20705 (301) 344-3915	Citrus canker	E. Civerolo
Bee Research Lab. USDA-ARS Plant Sciences Institute Bldg. 476, BARC-East Beltsville, MD 20705 (301) 344-2205	Bees, Mites, Diseases	W. Bruce, Q.O.
Beneficial Insects Research Lab. USDA-ARS 501 S. Chapel St. Newark, DE 19713 (302) 731-7330	Exotic arthropod parasites and predators of arthropod pests. Also: Limited quar. clearance and further ship- ment of exotic weed-feeding arthr., phyto- and entomo- genous nematodes, pollinators, dung beetles and entomopathogens.	R. Fuerster, Res. Leader L. Ertle, Q.O.

List of existing and planned quarantine facilities. -- Continued.

Laboratory	Target and/or Natural Enemy Organisms	Responsible Individual(s)
Hoboken Methods Development Center USDA-APHIS S&T 209 River St. Hoboken, NJ 07030 (202) 659-9099	Khapra beetle	R. Berninger, Ctr. Director
Otis Methods Development Ctr. USDA-APHIS S&T Otis ANGB, MA 02542 (508) 828-9354	Arthropods for biological control	C. Schwalbe, Ctr. Director
Foreign Disease- Weed Science Research Lab. USDA-ARS Ft. Detrick, Bldg. 1301 Frederick, MD 21701 (301) 663-7344	Exotic plant pathogens for biological control of weeds	W. Dowler, Res. Leader W. Bruckart, Q.O.
Plant Germplasm Quarantine USDA-APHIS PPQ Building 320 Beltsville, MD 20705	Containment for macro- arthropods	R. Brittingham, Q.O. in Charge
Grassland Soil & Water Lab. USDA-ARS 808 E. Blackland Rd. Temple, TX 76502 (817) 774-1201	Exotic arthropods for con- trol of brush and range weeds	C. Deloach, Res. Leader P. Boldt, Q.O.
Biological Control of Insects Lab. USDA-ARS P.O. Box 7629 Columbia, MO 65205 (314) 875-5361	Exotic arthropod parasites and predators of arthropod pests. Also: Receipt and diagnosis of exotic entomo- pathogens.	A. McIntosh, Res. Leader

List of existing and planned quarantine facilities. -- Continued.

Laboratory	Target and/or Natural Enemy Organisms	Responsible Individual(s)
Biological Control Laboratory USDA-APHIS PPQ P.O. Box 2140 Mission, TX 78572 (512) 585-8344	Exotic natural enemies of arthropod pests.	L. Wendel, Lab. Director P. Parker, Q.O.
Fruit Fly Rearing Laboratory USDA-ARS 509 W. 4th St. Weslaco, TX 78596 (512) 565-2423	Rearing of <i>Anastrepha ludens</i> and <i>A. obliqua</i>	A. E. King, Lab. Director D. Moreno, Q.O.
Biological Control of Weeds Res. Lab. USDA-ARS 800 Buchanan St. Albany, CA 94710 (415) 559-5826	Exotic weed-feeding arthropods	C. Turner, Lead Scientist D. Perkins, Q.O.
Bee Biology and Systematics Lab. USDA-ARS Utah State Univ. Logan, UT 84322 (801) 750-5310	Exotic pollinating insects.	J. Vandenberg, Res. Leader D. Veirs, Q.O.
Stoneville Research Quarantine Fac. USDA-ARS Jamie Whitten Delta States Agr. Research Center P.O. Box 346 Stoneville, MS 38776 (601) 686-2311	Exotic natural enemies of arthropod pests and exotic weed-feeding arthropods. Endemic plant pathogens for weed control.	D. Hardee, Lab. Director W. Harrison, Q.O.

List of existing and planned quarantine facilities. -- Continued.

Laboratory	Target and/or Natural Enemy Organisms	Responsible Individual(s)
Whiteville Methods Development Ctr. USDA-APHIS S&T P.O. Box 279 Whiteville, NC 28472 (919) 648-4115	Weed containment.	R. Eplee, Ctr. Director
Facilities Maintained by States and Territories		
Beneficial Insects Quarantine Lab. Dept. of Entomology Virginia Poly- technic Institute & State Univ. Blacksburg, VA 24061 (703) 961-5832	Exotic arthropod parasites and predators of arthropod pests and host specificity study of exotic weed- feeding arthropods	D. Cochran Dept. Head L. Kok, Q.O.
Maryland Dept. of Agriculture 50 Harry S. Truman Pkwy. Annapolis, MD 21401 (301) 841-5870	Biological control of weeds	W. Gimpel, Chief P. Tipping, Q.O.
Biological Control Center Quarantine Lab. Texas A&M Univ. & Texas Agr. Expt. Sta. College Station, TX 77843 (409) 845-2516	Exotic arthropod parasites and predators of arthropod pests.	F. Maxwell, Dept. Head M. Rose, Q.O.
Dept. of Plant Pathology Kansas State Univ. Manhattan, KS 66506 (913) 532-6176	Exotic bacterial pathogens.	J. Leach

List of existing and planned quarantine facilities. -- Continued.

Laboratory	Target and/or Natural Enemy Organisms	Responsible Individual(s)
Insect Quarantine Laboratory Dept. of Entomology Montana State Univ. Bozeman, MT 59717 (406) 994-4892	Exotic weed-feeding arthropods.	J. Littlefield, Q.O.
Quarantine Lab. Hawaii Dept. of Agriculture 1428 S. King St. Honolulu, HI 96814 (808) 548-7172	Exotic parasites and pred- ators of arthropod and snail pests and exotic weed-feeding arthropods.	G. Funasaki, Chief L. Nakahara, Q.O.
Quarantine Lab. Dept. of Entomology Univ. of California Riverside, CA 92521 (714) 787-5701	Arthropod parasites and predators of arthropod and snail pests, terrestrial weed-feeding arthropods, and aquatic weed-feeding arthropods and fish. Also: Limited receipt and diagnosis of exotic entomopathogens.	G. Gordh, Supervisor S. Warner, Res. Assoc.
Dept. of Nematology Univ. of California Riverside, CA 92521 (714) 787-3106	Exotic nematodes.	S. Van Gundy
Pest Exclusion Br. California Dept. of Food & Agr. 1220 N. Street Sacramento, CA 95814 (916) 445-4521	Karnal bunt.	T. Matsumoto
Dept. of Plant Pathology Montana State Univ. Bozeman, MT 59717 (406) 994-5157	Exotic plant pathogens.	Unfilled

List of existing and planned quarantine facilities. -- Continued.

Laboratory	Target and/or Natural Enemy Organisms	Responsible Individual(s)
Biological Section Plant Pest Control Branch Division of Plant Ind. Dept. of Agriculture Honolulu, HI 96810 (808) 548-7123	Exotic plant pathogens.	N. Nagata
Dept. of Plant Pathology Univ. of Hawaii 3190 Maile Way Honolulu, HI 96822 (808) 948-8329	Exotic bacterial pathogens.	A. Alvarez
Quarantine Lab. Div. of Biological Univ. of California 1050 San Pablo Ave. Albany, CA 94706 (415) 642-7191	Exotic arthropod parasites and predators of arthropod pests. Also: Limited receipt and diagnosis of exotic entomopathogens.	L. Caltagirone, Div. Chair J. Hamai, Q.O.
Quarantine Lab. Dept. of Entomology Univ. of California Davis, CA 95616 (916) 752-6935	Exotic arthropod parasites and predators of arthropod pests.	R. Washino, Dept. Chair L. Ehler, Q.O.
Biological Control Quarantine Lab. Hawaii Field Research Center Hawaii Volcanos National Park c/o G. P. Markin USDA Forest Service 1643 Kilauea Ave. Hilo, HI 96720 (808) 967-7122	Exotic phytophagous in- sects for control of weeds of native Hawaiian forests.	V. Tanimoto, Committee Chair C. Conrad, Res. Leader G. Markin, Q.O.

List of existing and planned quarantine facilities. -- Continued.

Laboratory	Target and/or Natural Enemy Organisms	Responsible Individual(s)
Beneficial Insects Introduction Fac. College of Agr. & Life Sciences Agricultural Expt. Sta. Univ. of Guam, GU 96913 (671) 734-3113	Exotic natural enemies of arthropod and weed pests.	R. Muniappan, Res. Leader D. Nafus, Q.O.
Division of Plant Industry Florida Dept. of Agr. & Consumer Services P.O. Box 1269 Gainesville, FL 32602 (904) 372-3505	Exotic plant pathogens.	J. Miller
Biological Control Laboratory Florida Dept. of Agriculture & & Consumer Serv. P.O. Box 1269 Gainesville, FL 32602 (904) 372-3505	Exotic arthropod parasites and predators of arthropod of arthropod pests and exotic arthropods for control of terrestrial and aquatic weeds, including host specificity testing.	H. Denmark, Bureau Chief F. Bennett, U. of Florida G. Buckingham, USDA-ARS A. Hamon C. Bennett, Q.O.
Insect Quarantine Facility Plant Industry Div. N. Carolina Dept. of Agriculture P.O. Box 27647 Raleigh, NC 27611 (919) 733-6930	Exotic natural enemies of arthropod pests.	C. Nalepa, Q.O.
Gypsy Moth Contain- ment Facility Dept. of Entomology Univ. of Georgia Athens, GA 30602 (404) 542-7888	Research on gypsy moth host preference.	C. Berisford

List of existing and planned quarantine facilities. -- Continued.

Laboratory	Target and/or Natural Enemy Organisms	Responsible Individual(s)
Non-governmental Facility		
American Type Culture Collection 12301 Parklawn Dr. Rockville, MD 20852 (301) 881-2600	Exotic plant pathogens.	R. Stevenson
Facilities under Construction		
Ameriflora Suite 321 941 Chatham Lane Columbus, OH 43221 (614) 457-9292	International Horticulture exhibit for cut flowers (1992).	J. Peterson, Exec. Director
Plant, Soil & Nutrition Lab. USDA-ARS Tower Road Ithaca, NY 14853 (607) 255-2456	Fruit flies and Russian wheat aphid	R. Carruthers, Res. Leader
American Cyanamid Inc. P.O. Box 400 Princeton, NJ 08543 (609) 799-0400	Genetically-engineered insect viruses targeted to Lepidoptera.	B. Black, Q.O.
Dept. of Plant Pathology Univ. of Florida Gainesville, FL 32611 (904) 392-7239	Exotic plant pathogens. Genetically-engineered organisms.	D. Gabriel, Q.O.

Foreign Exploration Considerations *F. D. Bennett*, Professor, Department of Entomology and Nematology, University of Florida, Gainesville, Florida.

Foreign exploration is the key component of classical biological control. Until natural enemies become available, the domestic components cannot proceed. All too frequently, available funding is inadequate to undertake this phase in sufficient depth. Usually there are no “emergency” or contingency funds set aside to initiate a prompt biological control response when a new foreign pest turns up although money on a much larger scale is usually made available for eradication programs. For every month that expires before funds and other resources are committed to foreign exploration commences, there is a similar or longer delay before biological control is achieved.

In the United States, foreign exploration for natural enemies of arthropod pests and weeds is organized in several ways. Organizations such as the International Institute of Biological Control contract to undertake in-depth studies and to provide cultures of selected biological control agents. ARS maintains a series of permanent overseas bases in strategic areas for the same purpose. State and university scientists are employed to conduct foreign exploration on a full-time or part-time basis to service problems of particular importance to their state. Foreign colleagues often cooperate by supplying natural enemies. All of these approaches have merits and also limitations. The approach to foreign exploration depends on the type of pest and is not always the same. Timing is much more critical for temperate than for tropical pests, and there is often very little seasonal latitude in searching for natural enemies of univoltine species. States such as Hawaii and Florida frequently have pest problems unique to their state, and hence, are less likely to attract federal support to explore for natural enemies. They require the flexibility to act promptly and independently when a new pest appears.

The current protocol for obtaining permits to import foreign arthropod natural enemies of pests and weeds works well, and the time elapsing between application for and issuance of permits is acceptable. The rapidity with which foreign exploration commences will also vary with the area or country where the pest originates. Authority to travel or collect in the country of origin may not be easily obtained and foreign exploration in the most

optimum area can be delayed or refused indefinitely. In such cases, close cooperation and approaches through diplomatic channels may be required.

Action Program Considerations *R. C. McDonald, W. A. Dickerson and H. M. Singletary*, Biological Control Administrator, Plant Protection Administrator, and Director, Plant Industry Division, North Carolina Department of Agriculture, Raleigh, North Carolina.

North Carolina has enacted two statutes that place it in a unique situation nationally regarding biological control and quarantine issues. These are the North Carolina Biological Organism Law (Article 4D of Chapter 106 of the General Statutes of North Carolina as adopted in 1973), and the Genetically-engineered Organisms Act (Chapter 106, Article 64 of the General Statutes of North Carolina, 1989). We will be speaking at the Quarantine Workshop about the impact of these laws on future developments in biological control and their bearings on action program considerations.

The North Carolina Biological Organism Law mandates that the state has the authority to establish standards of positive identification, purity of culture or colony, and freedom from disease and hyperparasites of biological organisms and standards of competence and responsibility for the private practitioner engaged in the propagation, use, distribution, release, or sale of biological organisms. In concert with this law, the North Carolina Genetically-engineered Organisms Act gives the state the authority to regulate the release and commercial use of genetically-engineered organisms in order to protect agriculture, public health, and the environment.

The state has a threefold responsibility of efficacy, regulation, and development of biological products. First, commercial products must be proven to be efficacious and possess no deleterious effects on non-target organisms. Second, the state is ultimately responsible for the introduction of an organism, and must review information and make decisions to approve or disapprove introductions based on risk analysis. Third, it is important that we strike the correct balance between regulation and restrictions such that development of biological products is not unnecessarily hindered.

Therefore, we must further define the concept of pest risk analysis. As we gain more sophistication in handling organisms, there should be the development of various levels of quarantine along the line of the Centers for Disease Control in Atlanta, Georgia. The philosophical dangers which have not slowed the development of advances in biotechnology should not also slow the advances in biological control quarantine technology. This should allow us to consider the importation in quarantine of exotic pests due to resident expertise on containment and potential for research into their control.

Session II: Quarantine Procedures

Importation Moderator: *L. E. Caltagirone*, Professor, Division of Biological Control, University of California, Berkeley, California.

Approval and Permits *P. J. Lima*, Staff Specialist, BATS, PPQ, APHIS, Hyattsville, Maryland.

In carrying out its mission to “protect American agriculture”, APHIS enforces three Acts of Congress: the Plant Quarantine Act of 1912, the Federal Plant Pest Act of 1957, and the Federal Noxious Weed Act of 1974. These Acts provide APHIS the authority to restrict or prohibit the movement of potential pests. Plant pest permits are legal authorizations allowing movement into or through the United States, and are obtained by completion of PPQ Form 526, “Application and Permit to Move Live Plant Pests and Noxious Weeds.” Applications are evaluated by receiving states and by PPQ, but PPQ has final authority. In issuing permits, APHIS must comply with statutes enforced by other federal agencies, including the Customs Service, the Centers for Disease Control (CDC), the Environmental Protection Agency (EPA), the U.S. Fish and Wildlife Service, and the National Park Service.

Before issuing an importation permit, APHIS evaluates pest risk. Risk evaluation considers the following six points:

(1) Potential of the organism to cause injury to U.S. agriculture.

(2) Adequacy of the containment facility to prevent escape.

(3) Purpose of the research, number of shipments requested, and need for field studies.

(4) Chance of establishment should the organism escape quarantine before being determined safe to agriculture and the environment.

(5) Experience, reputation, and risk awareness by the permittee and assistants.

(6) Ability to comply with requirements of individual states and other U.S. agencies

The TAG provides additional risk assessment for agents imported for the biological control of weeds.

Organisms that are approved for importation must arrive in escape-proof packages at U.S. ports of entry designated for inspection and clearance, must be forwarded directly to an APHIS-approved high security quarantine facility, and, in the case of arthropods, must have voucher specimens deposited with the ARS Systematic Entomology Laboratory (SEL). APHIS approves designs for construction of new quarantine facilities and modification of those existing. Quarantine facilities are built specifically for conducting research on prohibited organisms under escape-proof conditions.

Routing and Customs Problems *D. Gonzalez and F. E. Gilstrap*, Professor, Department of Entomology, University of California, Riverside, California, and Professor, Department of Entomology, Texas A & M University, College Station, Texas.

Needs Statement: Effective permits and a back-up system are essential to facilitate proper importation of live enemies to approved quarantine facilities in state agricultural experiment stations.

Characterization of Problems: Several kinds of problems occur at U.S. ports of entry. The general reason for these problems is that APHIS PPQ inspectors are often not informed regarding what a valid importation permit is or how it is to be handled. Some specific problems are as follows. (1) The PPQ inspector on duty requires “proof”

that live material in the shipping container is *exactly* the same as is approved in the permit. (2) The PPQ inspector on duty refuses to allow entry of material despite the importer's possessing a valid permit. (3) The PPQ inspector on duty opens the shipping container to verify the contents of the container in direct violation of the instructions on the permit. (4) The PPQ inspector on duty requires the importer to hand the inspector the *original* of the approved permit and will not accept a copy of the permit copy absent the original signatures of approving authorities. (5) The PPQ inspector is not present at the entry site and a supervisor is not available. When problems occur at the port of entry, possible outcomes are that shipped material is confiscated by the inspector and dies before eventually reaching the importing quarantine facility or that the importer is told to return the shipment to its country of origin, to leave the shipment and return to the port of entry the next day for further processing, or to leave the shipment until the PPQ supervisor is available, which may be seven or more days.

We recommend the following be implemented to minimize the described problems:

(1) A back-up system must be developed and implemented to assist biological control importations at ports of entry. This system must include the name and phone number of a designated, responsible official. The designated official must have the authority to inform a local PPQ inspector of necessary information and to give the approval for moving a shipment to an approved quarantine facility.

(2) Written guidelines for approving entry of biological control agent shipments must be developed by PPQ. The guidelines must include names of lead PPQ officers (i.e., Officers in Charge) at specified ports of entry. Copies of these guidelines must then be housed at each designated port of entry. The guidelines must explain the validity and use of the PPQ permits and provide a phone number (perhaps an "800" number) for further explanation if a question develops.

(3) The language on PPQ Forms 526 and 599 must be changed to reflect the true nature and contents of importation biological control. The current permit request (PPQ Form 526) is an "Application and Permit to Move *Live Plant Pests*", and the current shipping label (PPQ Form 599) says that the package contains "*Living Plant*

Pests or Pathogens." Nothing is said about the beneficial nature of the activity or contents of the package. After more than 100 years of biological control, we do not have a specific application form and authorization permit to move "*beneficial insects*." This flaw is exacerbated by the fact that PPQ inspectors are necessarily locked into a mind set of *preventing* entry of materials. The language (and Form) of the current permits must be changed somehow to reflect correctly the beneficial nature of the shipment. The goal of the shipment is to import BENEFICIAL arthropods and exceptional quarantine safeguards are built into the importation biological control activities.

(4) APHIS PPQ must become a true partner with biological control specialists. At present, local PPQ inspectors are often genuine adversaries: they have no alternative to the "book," and they often will not or do not care about, facilitate, or cooperate in the importation process. Only by engaging in a true and functional partnership can solutions to the problems be facilitated. The goal of PPQ and biological control specialists should be the proper importation of natural enemies.

Quarantine Receipt and Handling Moderator: A. C. Schmidt, Biocontrol Advisor, Biosystematics Research Centre, Agriculture Canada, Ottawa, Canada.

Levels of Containment Required W. L. Bruckart, Research Plant Pathologist, Foreign Disease-Weed Science Research Laboratory, ARS, Frederick, Maryland.

Importation and interstate movement of plant pests and, more recently, transgenic organisms is regulated by the federal government through APHIS. Many of the bacteria, fungi, insects, nematodes, and viruses considered for biological control are subject to regulation because they are plant (weed) pests or they are related to pests of agricultural importance. Generally, these potentially beneficial organisms are not well understood, because they occur on target species of relatively little importance in their native ranges and therefore have received little scientific attention. The knowledge that devastating results have occurred from accidental introductions of plants, plant pathogens, insects, and nematodes justifies measures for strict control of candidate biocontrol organisms until their safety can be verified through

scientific research. Understanding the biology of these organisms and their relatives has resulted in development of strategies for their containment, and a number of guidelines have been published for this purpose. It is physically possible to contain organisms for research purposes and certainly appropriate if they are of undesirable or unknown stature. It is more practical to have several tiered levels of containment for organisms that vary in their threat to agriculture or in their ease of containment. However, discussion and debate continues regarding which specific organisms pose a threat and which level of containment is sufficient for their study. Generally, if the organism is exotic or of unknown stature, the highest level of containment applies; it is guilty until proven innocent. Features of a greenhouse or laboratory capable of the highest levels of containment include double-door entry, negative air pressure, double-door autoclaves, waste water collection, HEPA filters, showers or coveralls for personnel, rodent and pest control, and black light traps. Mitigating factors may justify a reduced level of containment, such as insects that have no winged form or fungi that do not produce airborne spores.

Quarantine Officer Duties and Responsibilities

L. K. Etzel, Quarantine Officer, Division of Biological Control, University of California, Berkeley, California.

Quarantine is a critical process in the importation of beneficial organisms for classical biological control projects. For the process to operate effectively, the quarantine officer in charge must rigorously perform his duties and responsibilities, and must possess a broad knowledge of legalities and procedures and of the taxonomy, biology and propagation of the organisms which will be handled.

The quarantine officer needs to be familiar with the laws and regulations involved in the importation program, including those pertaining to the receiving facility, to importation and release permits, and to procedures. All elements of the process must contribute to the prime requirement and purpose of quarantine--that no harmful or unwanted organisms be introduced into the environment.

The procedures of receiving overseas shipments, passing them through customs and agricultural inspection, and processing them in quarantine can be facilitated if the

quarantine officer has a close working relationship with regulators and inspectors and with project leaders. Another crucial aspect of quarantine work for which the quarantine officer is responsible is documentation. Not only must an audit trail be established for all beneficial organisms received and propagated, but voucher specimens also need to be prepared and provided as required.

A broad taxonomic knowledge by the quarantine officer of the kinds of organisms to be processed will provide an important key to their handling. The more detailed the identification of an organism, the greater is the amount of biological information that can be obtained from the literature, and the faster can the organism be evaluated as a potential beneficial species that can be field released. Nonetheless, the quarantine officer must also have a general knowledge of biologies and of rearing techniques and requirements, so that he can perform the tests necessary to prove that an unknown organism can be safely released from quarantine.

Although most of the duties and responsibilities of a quarantine officer would apply regardless of the types of organisms involved, certain responsibilities for maintaining unique facilities and performing unique procedures would apply for quarantined organisms as disparate as arthropods and microorganisms.

Training for a quarantine officer should include not only a formal curriculum related to the specific kinds of organisms processed in quarantine, but also should include apprenticeship training, and possibly, periodic refresher workshops. Because of the great importance of documentation in the quarantine process, training in computer skills would also be very useful.

A quarantine officer should above all have the capacity and temperament to attend to the prime security requirement of the quarantine facility. However, that person should also be knowledgeable, persevering, dedicated, and resourceful.

Quarantine Receipt and Handling *L. R. Ertle*, Quarantine Officer, Beneficial Insects Research Laboratory, ARS, Newark, Delaware.

Beneficial material arriving at a quarantine laboratory will be in one of three stages or conditions: adults, immatures which will soon emerge, and immatures in diapause. Within the confines of the designated incoming package handling area the initial stages of receipt, handling and processing occur. After opening the consignment's outer packaging and locating any included documentation, each internal shipping carton is individually examined and the necessary supplies gathered to process the material inside. Adult specimens must be separated from the shipping carton and individually placed in vials for examination and identification by the quarantine officer. Following identification, the healthy adult specimens are re-collected into either a holding or trans-shipping carton. Immature specimens about to emerge are examined primarily to determine the type of holding container and moved to an emergence incubator. Diapausing specimens follow the same routine and are eventually placed into a cold storage incubator for emergence at a later time. During this process of identification and handling, accurate records are maintained describing the process, unusual events, behavioral traits, and the number and sex of specimens handled. Temporary incoming shipment-identification labels are attached to every container holding the specimens. The process of examination and identification is repeated as the adults emerge from the other stages. Accurate identification of all specimens is the key to all quarantine operations. Reference and voucher specimens are selected, mounted, labeled, and sent to taxonomic specialists for RUSH determinations. Identified beneficial species that have received quarantine release clearance are taken to the packing and shipping area for shipment and document preparation. The remaining species are cultured for one or more generations to study and evaluate them as candidates for eventual quarantine release.

Operation of a Biological Control Quarantine Laboratory *M. Rose*, Quarantine Officer, Department of Entomology, Texas A & M University, College Station, Texas.

The operation of the quarantine laboratory was discussed in relation to biological control of non-plant-feeding arthropods. The key areas of discussion were biological control, tenets of quarantine, space, and operational

procedures, including purpose, safeguards, functions, responsibilities, quarantine entry, regulations, records, identifications, biological studies, consignment, vouchers, and egress from quarantine. Further emphasis was given to documentation and personnel, particularly in terms of the character of quarantine laboratories constructed and operated by state institutions. The role of the quarantine laboratory in biological control and steps to achieve successful introduction of new natural enemies were presented diagrammatically.

Other Aspects of Quarantine Moderator: *F. E. Gilstrap*, Professor, Department of Entomology, Texas A & M University, College Station, Texas.

Taxonomic Problems and Procedures *M. E. Schauff* and *A. Y. Rossman*, Research Entomologist, SEL, ARS, and Research Leader, Systematic Botany and Mycology Laboratory, ARS, Beltsville, Maryland.

The effective importation and release of natural enemies through quarantine facilities is heavily dependent on taxonomic support. Prompt and accurate identifications are often critical to release programs and these identifications are often only available from specialists who may be far removed from the quarantine site. We view many of the problems with obtaining timely services as stemming from basic flaws in communication between workers at quarantine facilities and systematists. Many of these problems can be alleviated by adherence to proper procedures and through enhanced communication and awareness of the needs of both the identifier and the user.

Accurate identifications of target organisms as well as beneficials is of extreme importance, but problems persist. For example, many important groups, such as leafhoppers and rusts, are currently without a resident ARS expert who is competent to make identifications and do vital research. The lack of basic systematic information about organisms useful to biological control continues to be an impediment and without it many decisions can not be properly made. Communication is especially important since identifications compete for time with research projects. While service is an important part of the duties of most systematists in USDA, supplying identifications is often not their primary mission. Systematists need to be

aware of the goals of ongoing biological control programs and the time frame of importation and release efforts. If heavy use of identification services is expected, systematists need to know well in advance so that time can be scheduled. Identifications, especially of foreign material, can be very time-consuming.

Adherence to proper procedures is extremely important to a systematist's ability to provide accurate identifications. Nevertheless, submittal of specimens need not be overly complex or burdensome for submitters. Of primary importance is the condition of specimens and the means of mounting or preservation. When in doubt, it is best to check with the specialist prior to collection of specimens. The appropriate preservative or method of mounting may vary even among genera of a single family.

Besides the obvious need for identifications, systematic research supplies critically important information needed to make rational decisions about introductions. This information can influence the ability to obtain release permits, suggest approaches for manipulating beneficial organisms, and increase the overall effectiveness of biocontrol organisms both genetically and ecologically.

We recommend that scientists involved in quarantine projects consult with a systematist who has experience in the target group prior to initiation of the project. It is also essential that there be increased support for taxonomic research and services, especially in groups where expertise is currently lacking.

Storage of Microbials *R. A. Humber*, Microbiologist,
U.S. Plant, Soil and Nutrition Research Laboratory, ARS,
Ithaca, New York.

Techniques for storing the germplasm of living microbes are essential for virtually every phase of research and development focusing on the use of pathogenic fungi, protozoa, bacteria, and viruses for the biological control of pests. Centralized microbial germplasm repositories should serve as the principal quarantine receiving sites for the importation and redistribution of non-indigenous microbes and as the main locations for identification services and systematics research on these organisms. As such, these centralized repositories should build collections of preserved specimens in addition to living cultures.

Several techniques for long-term preservation of microbial germplasm are available. Cryopreservation in mechanical freezers at -80 or -120°C, in the vapor phase over liquid nitrogen (-120 to -190°C), or immersed in liquid nitrogen (-196°C) may be most suitable for long-term maintenance in central germplasm repositories, but may be too expensive or impractical for smaller laboratories working on more limited research and development projects. Lyophilized (freeze-dried) preparations seem to be wholly satisfactory for preserving the sorts of bacteria and viruses useful for biological control. These major preservation techniques cannot be used interchangeably since, for example, many fungi with large cells or high vacuolar volumes can be frozen, but do not tolerate freeze drying.

Short-term storage or maintenance of relatively low numbers of separate lines of microbes that can be grown in pure cultures usually requires less rigorous storage conditions. Many techniques may be suitable for such needs. These include such techniques as serial transferring, refrigeration of cultures, and storage under mineral oil or sterile distilled water.

A serious problem for all germplasm repositories is that there is no absolutely ideal storage method that can guarantee the recovery of an organism from storage without any effects to its viability, overall phenology, or, in the case of biological control agents, such key properties as virulence and pathogenicity. There is no way to predict what sorts of losses may be experienced during long-term storage of microbial germplasm. Clearly, there is a pressing need for intensive research to be pursued to seek improvements in germplasm storage technology that would be of marked benefit to all segments of biology and to all countries of the world.

The method of long-term storage used for any microbe may strongly affect the form in which that organism is redistributed from a quarantine site. Lyophilized fungi, bacteria, or viruses can be most safely and conveniently moved in their intact lyophil tubes. Microbes that have been in cryostorage must be revived and transferred at the repository; they can be redistributed only as living cultures. Practical experience indicates that there is little practical danger in the routine use of standard mail and parcel carriers to move most microbial biological control agents, however.

Screening Classical Weed Biocontrol Projects and Agents (See also Appendix 2) *P. Harris*, Director, Biological Control of Weeds Research, Research Station, Agriculture Canada, Regina, Saskatchewan, Canada.

Classical weed biocontrol is both done and regulated by government in the public interest. Screening is a regulatory requirement that is expensive and slow, so it is important that it is really needed and is administered efficiently. Regulation is needed to protect three public interests: that biocontrol of a weed is likely to be beneficial, that the candidate agent has a predictable host range, and that agent establishment will be beneficial. This requires that weeds should be approved for biocontrol before agents are screened. To ensure that there is wide public support, the TAG should publish proposals that are approved in principle for public comment. Formal approval would be given after consideration of these comments. Agents proposed for release should be reviewed by an Agent Review Group, which should also approve the screening protocol.

Presently too much emphasis is put on the results of “no choice” feeding tests, and more weight needs to be given to host range and ecological data from the region of origin. More taxonomic help is needed during agent screening, and agents should not be released from other regions or host plants without studies to show that they are the same as those screened. Also, once a disease-free, well-adapted agent is established, further mass release of overseas stock should not be permitted.

Summary *F. E. Gilstrap*, Moderator.

Drs. Schauff and Rossman characterized “Taxonomic Problems and Procedures.” According to them, effective importation and release of natural enemies through a quarantine facility is heavily dependent on taxonomic support. They discussed problems in taxonomy (i.e., absence of taxonomists in key taxa, logistics of taxonomist/project location, absence of materials/tools in key taxa), the importance and benefits of early notification of taxonomists in developing an importation program, procedural requirements (proper preparation of specimens for shipping, identification, curation), constraints which limit a taxonomist’s ability to perform needed functions, and the broad range of more recent tools that make more accurate determinations possible (i.e., com-

puter technology, molecular systematics, and morphological procedures). The bottom line is that taxonomy is an essential ingredient in successful biological control, is presently inadequately funded, and can be improved if included as a funded ingredient with taxonomist participation right from the beginning of project development.

Dr. Humber discussed the storage of microbials. According to him, microbials can often be stored for long periods of time, but some approaches are better than others depending on the type of organism to be stored. Humber discussed microbial storage using refrigeration, perpetual transfer, sterile water, host cadavers and cryogenesis. Humber stressed that storage centers of microbials should also be centers of expertise on microbial taxonomy and that long-term storage is generally an expensive undertaking. Humber emphasized, however, that microbial germplasm repositories are essential ingredients of microbial biological control and microbe taxonomy.

Dr. Harris reviewed host-range testing and the process of approving candidate organisms for release and biological control of weeds. Harris expressed concern that the regulatory authorities are too rigid defining a “plant pest,” and thereby prevent releasing or considering excellent prospective candidates for controlling a target weed. Harris discussed three aspects of weed biological control agent approval. This discussion was in the context of three considerations: (1) biological control of a target weed must be in the public interest, (2) the control agent has a predictable host range, and (3) the released agent will do more good than harm. Harris suggested that in addition to a TAG for decisions on candidate weed enemies, an Agent Review Group should be appointed to advise on simplifying the agent screening requirement when possible. In Harris’s view, too much emphasis is placed on results of “no choice” feeding tests in evaluating candidate agents for importation. He encouraged placing much greater emphasis on the natural host range and ecological requirements of candidate agents.

Release from Quarantine Moderator: *G. R. Buckingham*, Research Entomologist, Aquatic Plant Management Laboratory, ARS, Gainesville, Florida.

Decision to Release from Quarantine *R. M. Parry, Jr.*, Deputy Assistant Administrator, Office of Cooperative Interactions, ARS, Washington, D.C.

The release of an organism from quarantine to evaluate its biological behavior in the environment is a complex decision. In one sense, it may be the first direct exposure of a scientist to the applicable federal and state regulations, which govern the issuance of a permit to release an exotic organism into the United States. Other laws may be involved, including the National Environmental Policy Act, which could necessitate preparation of an Environmental Assessment (EA) of the potential impacts on the human environment, the Endangered Species Act, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which could require submission of an Experimental Use Permit (EUP) to the EPA. A public information program may also be required, depending on the scope of the proposed release, if significant issues arise during preparation of the permit, the EA, or the EUP. The overlapping jurisdiction of these regulations and laws, when combined with their poorly defined data requirements, can present a formidable obstacle to the successful establishment of a biological control agent.

This complex clearance process can be significantly improved by the establishment of objective scientific criteria for biological safety which are broadly acceptable to experts in the field. The criteria should capture elements of ecological risk assessment to guide decision makers on weighing the potential for adverse impact. Also, consideration is needed of the legal framework that will be used by a regulatory agency to apply the criteria. This Workshop has an opportunity to take the first steps to establish a rational structure for clearing biological control materials from quarantine which can significantly speed development of needed pest control alternatives.

Interstate Shipment *B. P. Singh*, Staff Officer, BATS, PPQ, APHIS, Hyattsville, Maryland.

Importation, interstate movement and release of live plant pests, pathogens, vectors and biocontrol agents are

imperative for scientific research and industrial development. Interstate shipment consists of the movement of organisms from one state to another within the United States. While it is necessary to move biocontrol agents, it is also important that these organisms be kept under control because of the risk they may pose to U.S. agriculture.

To prevent catastrophic outbreaks, the Plant Quarantine Act of 1912 and the Federal Plant Pest Act of 1957 were enacted by Congress to regulate importation, interstate movement and release of pests, including arthropods, pathogens, vectors, biocontrol agents, and articles which harbor these organisms. These Acts provide authority to APHIS to restrict or prohibit unauthorized movement of biocontrol agents. Conventional biocontrol agents (i.e., those that are not genetically-engineered) are currently regulated under 7 CFR Part 330. This Part is under revision at the present time.

After importation and testing under containment, some potential biocontrol agents are shipped interstate for further testing in the field or various other purposes. For such interstate movements, an authorization for the movement is granted by a permit. The applicant may obtain the necessary application materials from the BATS unit, PPQ field offices, and state regulatory officials.

Upon completion of designated sections of the Permit Request Form, the applicant forwards the form to appropriate state regulatory official of the state of destination. The state regulatory official reviews the application and directs it to BATS with recommendations. BATS conducts pest-risk analysis, weighs risk against benefits, and considers state comments prior to issuing a permit. If the BATS decision is to grant a permit, applicable conditions are stipulated on the permit for the containment or release and appropriate labels are issued to facilitate the shipment. In case of denial, copies of the disapproved permit are dispatched to the state, PPQ regional office, and the applicant with the reasons for disapproval.

Discussion *G. R. Buckingham*, Moderator.

Q: Is a permit needed for interstate shipment if the organism is already present in the United States?

A: For pathogens, a permit is needed if the pathogen has been released in one state or only a few states. If it has

been released in about five or more states, no permit is needed. Often the states themselves require a permit both for pathogens and insects. PPQ requires a permit for the first release of a non-plant-feeding beneficial, but only courtesy permits for release in subsequent states. Plant-feeding insects need permits for each state.

Q: If one wishes to move an exotic pathogen from a quarantine facility to other laboratories for study, not field release, is a permit needed?

A: Yes, you would need a permit.

Q: What type of permit is needed for shipments to Puerto Rico? A foreign source permit or an interstate permit?

A: A foreign source, red and white, permit is needed.

Q: How many requests for interstate shipment of entomopathogens does PPQ receive annually?

A: About 10, mostly from Dr. Humber's culture collection. Approximately 300-500 consignments a year are moved from Dr. Humber's containment facility to other laboratories under a broad agreement with PPQ. These are not for release. Phil Lima is informed about all consignments.

Q: Are EAs prepared for every permit to release a weed control agent?

A: Case law has finally caught up with the biocontrol permitting process and NEPA requirements, mostly because of the interest in regulation of genetically-engineered organisms. An EA is necessary in all major actions. If APHIS issues a permit, it must report an EA. The permitting process drives the need for an EA.

Q: Can an EA be prepared using the document submitted to the TAG for release of weed control agents?

A: That document can be used to prepare an EA which is prepared to inform the public that there is a finding of "No Significant Impact" (FONSI) if the permit is issued.

Q: Will actions concerning predators and parasitoids need an EA?

A: It depends if the permitting is a major action. If an EA is prepared, the EA might not need as much information as some other EAs.

Q: Shouldn't the EA lead to a "Finding of No Significant Negative Impact" rather than a FONSI? Obviously, a successful biocontrol agent will have a positive impact.

A: "Significant" is used in the context of the NEPA act not

in the context of everyday usage. It is used in the context of public debate. The permitting may or may not have a significant impact if it is a small action. The way the discussion is written can be very important. If the permitting will have a significant impact either positive or negative, an Environmental Impact Statement (EIS) will be needed.

Q: If a PPQ Form 526 is submitted for release of a parasite, will APHIS prepare an EA?

A: Yes, for most Form 526 permitting actions.

Q: How much time is needed to prepare an EA?

A: Soon, APHIS will have a 120-day maximum for preparation of an EA.

Q: Would a completed form that includes information needed for preparation of an EA help you complete the EA?

A: Yes.

Q: If we have studied an endemic entomopathogen at a certain location, but wish to import an exotic strain of that pathogen for release at that location because the endemic strain is ineffective, will an EA be necessary?

A: Yes. Recently, the introduction of a Turkish strain of a native rust found on a weed required an EA. We plan to provide criteria that we will use for preparation of the EA. In the case of new strains of endemic pathogens, not as much information will be needed as with some other EAs.

Q: APHIS might want to explore the possibility of preparing generic EAs for some permits. Is this possible?

A: Generic EAs generally lead to preparation of an EIS.

Q: Can a highly specific parasitoid group, for example, *Aphytis* spp. that infest armored scales, be excluded from the need of an EA?

A: It would be very, very difficult.

Q: How can we make an application for an exclusion?

A: The request for an exclusion must follow the criteria of NEPA, which are complicated. It would probably be easier to prepare an EA.

Q: How fast can an EA be prepared?

A: There is no pat answer to the question. They take different lengths of time to prepare. The maximum time is 120 days, but there is no minimum.

Q: Under what act is APHIS regulating biocontrol agents?

A: Under NEPA. If an organism is not regulated by APHIS, an EA will not be prepared by APHIS.

Q: Does APHIS have a document allowing it to regulate non-plant-feeding biocontrol agents, for example, an EIS?

A: No!

Q: When I submit requests to import different species of the scale parasitoids, *Aphytis* spp., I will keep submitting much of the same information. Is this okay?

A: Yes, we expect that many of our EAs will be very similar. This is not difficult with word processing programs.

Q: Are there regulations for nematodes?

A: If a permit is issued for release of a nematode, we will prepare an EA. If only a courtesy permit is issued, an EA will not be necessary.

Documentation Moderator: *L. Knutson*, Director, Biological Control of Weeds Laboratory, ARS, Rome, Italy.

Record Keeping *J. R. Coulson*, Entomologist, Biological Control Documentation Center (BCDC), ARS, Beltsville, Maryland.

The search for exotic organisms and their importation and release for biological control of pests in the United States provides not only an excellent opportunity, but I believe also an obligation, to collect and store the maximum amount possible of basic and applied research information of current and future value. There are generally three groups of potential users that benefit from such carefully prepared records: (1) ecologists and biological control practitioners (to include research scientists and “implementers” and their administrators); (2) animal and plant taxonomists; and (3) regulatory agencies and the general public. The benefits accruing to each group are discussed. The three current types of record keeping for U.S. programs involving introduction of *invertebrate* natural enemies of insects and weeds are briefly described. These are the Hawaiian, University of California, and USDA systems. The three forms used by the USDA system are illustrated; they were designed (1) to include all

relevant data, some of which are relegated to ancillary forms in other recording systems; (2) to provide communication between the shipper and recipient of the material, for collection/culture data from the former, and feedback information from the latter; and (3) to foster the regular retention of “representative specimens” (i.e., vouchers) of the natural enemy, and sometimes, of the host/prey. The use of these forms is included in the draft ARS Guidelines being discussed at this Workshop. As the number of biological control quarantine facilities and personnel expanded in the U.S. since the 1970s, the BCDC has attempted to establish the voluntary use of the USDA record forms by all U.S. biological control locations on a regular basis to provide a uniform, *nationwide* documentation system, with considerable success. A number of other federal, university, and state facilities now use one or more of the forms as a matter of course; others use variants of the University of California system, or systems specifically designed for their own programs. It is proposed formally at this Workshop that, at the very least, the most important of the three USDA forms, that recording the release of exotic material from quarantine (i.e., the AD-942) be placed into general use at *all* quarantine facilities throughout the U.S. through which exotic invertebrate organisms are introduced into the country. In view of the increasing effort in regard to the introduction and release of exotic *microbial* organisms for control of arthropods, weeds, plant nematodes, and plant pathogens, two other draft forms have been developed with the help of insect and plant pathologists to record (1) the introduction and (2) the field release of exotic microbial organisms for research and field establishment in the U.S. These are illustrated and their use is to be discussed during special sessions of this Workshop.

Voucher Specimens *J. B. Woolley*, Professor, Department of Entomology, Texas A & M University, College Station, Texas.

Voucher specimens are required in many kinds of biological research projects to document exactly what organisms were studied. They physically verify the identity of the organism(s) used in a study, and by so doing, ensure that a study which could not otherwise be repeated can be accurately reviewed or assessed. They are most critical when the study alters specimens such that future identification or verification of study material is impossible, or when improvements can be expected in species-level

taxonomy. In classical biological control projects, it is important to document the identity of the host and existing natural enemy complex before releases, field releases of new natural enemies, recoveries of colonized species, and any other species names used in any publications and reports.

To fulfill its function, a voucher specimen must have the diagnostic characters necessary for identification, be preserved in good condition, be adequately documented, and be maintained in good condition and readily accessible to other researchers. Species-level taxonomy is now under study in many groups of natural enemies. In addition, it is widely appreciated that entities below the species often differ in critical biological traits. Therefore, one should set up voucher specimens for all currently-recognized species (obviously, including sibling or cryptic species), material from different geographic regions, and entities with significant biological differences (i.e., biotypes, ecotypes, host races, etc.). It is important to set up voucher specimens even if entities appear to be anatomically identical. Entities to document include species from pre-release surveys (host and existing natural enemies), natural enemies that are consigned for laboratory work or field release (including original material of F_1 specimens), and first recoveries of each natural enemy. Long-standing cultures should be sampled periodically. Representatives of any other species names that are published (e.g., hyperparasites) should be vouchered.

Appropriate systematists should be consulted for advice on the preparation of voucher specimens. In cases in which information other than morphological characters is used for identification, one should obviously preserve material using appropriate methods, but in these cases, it is important to set up standard museum specimens also.

A repository of voucher specimens has two responsibilities: to preserve the specimens and related information and to make it easy for people to find and use them. Public or non-profit systematic research collections already have the facilities, staff, and administrative policies required for these functions; therefore, they should be utilized. Voucher specimens should be deposited into the proposed U.S. National Voucher Collection *or* in other established state or university collections. If a U.S. National Voucher Collection is established, I recommend incorporating it into the existing SEL collections along with the adequate support and resources. In any case, I do

not recommend keeping voucher collections separate, but integrating them into existing research collections. Appropriate documentation and record-keeping will ensure easy retrieval of specimens. All of the above recommendations are made to facilitate ongoing care and curation of material and ready access to specialists.

In addition to the usual locality, collector and host labels, voucher specimens should bear separate, distinctive labels with sequential voucher numbers and any accession numbers assigned in quarantine. A permanent, separate log should be kept and specimens should be referenced by unique accession numbers. Data in the log should include the place of origin, date, name and affiliation of collector, complete host information including determiner, method of collection or preservation if relevant, species determination, date and determiner. Additional information should include a brief summary of the research project and citations for publications, including theses, dissertations, and reports.

Voucher specimens should be required in most cases as a condition of publication by scientific journals. Authors should indicate the repository and provide the accession numbers of voucher specimens mentioned in publications.

In summary, the following steps can be followed in setting up procedures for voucher specimens. (1) Determine policy for vouchers and inform your staff. (2) Determine appropriate methods for curation of specimens. (3) Contact the anticipated repository and discuss your requirements. (4) Train specific personnel and make them responsible for setting up voucher specimens. *Do not* leave voucher specimens until the end of a project. Anticipate costs of voucher specimens and taxonomic support and include them in your proposal budgets if necessary.

Chapter III. Present Status of Biological Control Quarantine in the United States

Overview

Facilities for Arthropod Parasites/Parasitoids and Predators of Arthropod Pests of Plants; for Arthropod Parasites/Parasitoids, Predators, and Competitors of Arthropod Pests of Humans and Livestock

R. W. Fuester, Chair, Group 1.

There are currently 14 primary facilities for introduction of arthropod parasitoids, predators, and competitors in the continental U.S.: Newark, Delaware; Otis Air National Guard Base, Massachusetts (currently used for plant pests); Annapolis, Maryland; Raleigh, North Carolina; Gainesville, Florida; Homestead, Florida; Stoneville, Mississippi; College Station, Texas (two facilities, one state and one federal); Mission, Texas; Bozeman, Montana; Berkeley, California; Davis, California; and Riverside, California. In addition, there are facilities in Hawaii and Guam. Moreover, quarantines are being considered for construction in Providence, Rhode Island; Columbus, Ohio; Niles, Michigan; St. Paul, Minnesota; Little Rock, Arkansas; and Yakima, Washington. In addition, there is a currently uncertified facility at Columbia, Missouri.

Facilities for Arthropod-parasitic Nematodes

W. R. Nickle, Chair, Group 2.

Exotic arthropod-parasitic nematodes are generally received directly by various research facilities, and it was the general consensus that there is no need for “quarantine” facilities for these organisms. However, if these organisms are to be imported in their arthropod hosts, the shipments should be routed through quarantine facilities for arthropods.

Facilities for Invertebrate Natural Enemies of Weeds

P. C. Quimby, Chair, Group 3.

At present there are 11 quarantine facilities in North America for invertebrate natural enemies of weeds: Albany, California; Regina, Canada; Bozeman, Montana; Temple, Texas; Blacksburg, Virginia; Mission, Texas; Annapolis, Maryland; Gainesville, Florida; Stoneville, Mississippi; Hilo, Hawaii; and Whiteville, North Carolina. A facility is currently planned for Fort Lauderdale, Florida. Existing overseas screening facilities are located in Rome, Italy, and Delemont, Switzerland. Another is

being planned in Montpellier, France. The Bozeman and Stoneville quarantine laboratories work with arthropods and nematodes. All other quarantines work only with arthropods.

Facilities for Arthropod Pathogens *R. A. Humber*, Chair, Group 4.

There was no feeling that there is any major need for additional quarantine facilities to deal with microbial pathogens of arthropods. There is an adequate number and geographical distribution of laboratories treating the entire range of entomopathogenic microbes.

Facilities for Weed Pathogens *W. L. Bruckart*, Chair, Group 5.

Current locations include Frederick, Maryland, and planned state facilities at Honolulu, Hawaii; Bozeman, Montana; and Fayetteville, Arkansas.

Facilities for Natural Enemies and Antagonists of Plant Pathogens and Nematodes *G. C. Papavizas*, Chair, Group 6.

The field of classical biological control of plant pathogens and nematodes with the use of microbial pest control agents (MPCAs) is relatively new compared to the classical biological control of insects. It is only 10-12 years since plant pathologists and nematologists have begun in earnest to use MPCAs (e.g., hyperparasites, antibiotic-producing microorganisms, competitors for food and space, hypovirulent strains) for augmentation-type of control by applying such organisms to seeds, bulbs, tubers, soils, containers, soilless mixes, and as sprays on plants.

There are several principles and concepts we must try to understand in order to adjust our thinking and attitudes as far as containment and release of potential MPCAs are concerned:

(1) Potential MPCAs, especially those for control of soilborne plant pathogens and nematodes are immobile with very little or no chance for movement from the site of application. Therefore, they are easy to contain.

(2) Exotic potential MPCAs are almost exclusively imported as pure cultures. Even when small amounts of soils are imported, microorganisms are isolated and maintained as pure cultures and the soils are autoclaved.

(3) In plant pathology and nematology, we do not import potential MPCAs and use them in the field. Such MPCAs are imported for laboratory and growth chamber work to select one or two strains for field work.

(4) Every soil, cultivated or virgin, the forest litter, the decomposing organic matter, the plant rhizosphere and spermosphere from one part of the country to the other can provide us with potential MPCAs to last for many years. Every ounce of soil under our feet may contain several strains of such potential organisms.

(5) Quarantine needs and procedures should be based on the nature of the exotic organism and not on its intended use. In other words, an exotic microorganism that can be shipped in pure culture in a test tube, intended for testing in the U.S. as a MPCA, should not trigger a quarantine requirement just because the microorganism is intended for use in biocontrol. Stated another way, the intent to use an exotic microorganism for biocontrol purposes is not, of itself, justification for requiring that the microorganism be held and possibly studied in a quarantine facility before allowing it to pass onto the investigator responsible for bringing the microorganism into the U.S. For instance, there is currently no requirement, nor should there be any, for quarantine processing of organisms imported into the U.S. to be used in other jobs in agriculture (e.g., N-fixation, phosphate solubilization, straw decomposition, or uses other than plant defense against diseases).

the most current (i.e., as of January 1991) listing of U.S. biological control quarantine facilities (with the exception of an existing one in Guam and planned facilities in either Minnesota or Michigan and in Arkansas), but it may be useful to consult both lists and the overview comments above for complete information.

Detailed comments on subjects additional to those included in the Tables were provided by many of the respondents to the survey, including details on physical aspects of the facilities, on their activities, and on specific restraints encountered hampering many of the problems pointed out in other sections of these Proceedings. Copies of the completed questionnaires are on file in the ARS BCDC.

Reports of Existing and Planned Quarantine Facilities

In order to determine the status and needs of quarantine facilities in the United States, a survey of all known approved or planned facilities was conducted prior to the Workshop, using the illustrated questionnaire (Fig. 1). The following tables have been prepared based on the information received from the 22 existing and 9 proposed facilities that responded. It must be noted that the facilities listed in Table 1 differ from those included in the list provided by E. M. Imai, PPQ, in his presentation (q.v., Chapter II, pp. 10-17). It is believed that Table 1 provides

Figure 1. Questionnaire used to survey existing and planned quarantines.

Questionnaire for
Existing and Planned U.S. Biological Control Quarantine Facilities
Information for USDA Workshop on Biological Control Quarantine
Baltimore Maryland, January 14-17, 1991

For Existing Facilities:

1. Location, Description, and Means of Communication

- a. Title of Facility:
- b. Affiliation & Mailing Address:

- c. Size of Quarantine Area (Sq. Ft.):
- d. Insectary/Other Facilities Available to Facility:

- e. APHIS Approval: Date 1st Obtained: Date of Last Inspection:
- f. Names of Quarantine Officer and Other Primary Contact:

- g. Phone Nos.: Fax Nos.:
- h. Electronic Mail Availability: Name of System: None:
Mailbox No.:
- i. Reporting System: Periodic Reports Prepared (Nature & Frequency):
Report Availability:
Other Documentation Methods/Availability:

2. Mission, and Current and Possible Expanded Activity

- a. Types of Organisms Quarantined:

- b. Major Source(s) of Taxonomic Identifications (Organization/Locations):

- c. Part of Activity is: Research _____ % Service _____ %
- d. Current Volume of Traffic:
Average No. Shipments (Consignments)/Year Incoming:
Average No. Shipments (Consignments)/Year Outgoing:
% Operating Capacity of Facility Resources Used:
Average No. Outside Locations _____ Inhouse Scientists _____ Serviced/Year
- e. Available for Pass-Through for Other Organizations? No _____;
Yes _____ - at extra cost? No _____; Yes _____ \$ _____.

3. Other Comments (use reverse of questionnaire or separate sheets as needed)

- a. Major Problems/Constraints to Effective Quarantine Operation:

- b. During Workshop Session I on Quarantine Needs, plans permit attending Quarantine Facility representatives to speak (ca. 5-10 minutes). Do you wish to speak on a topic of your choice related to Quarantine needs?
Yes _____; No _____.

For Planned Facilities:

- 1. Construction underway? Give expected date of completion:
Please respond to any questions in Sections 1-3 above as may be possible.

 - 2. If construction has not begun, indicate probable date expected to begin, or comment on status of plans for facility:
-

Table 1. Existing and planned biological control quarantine facilities in the United States and its territories

Laboratory/Address	Acronym/Email	Responsible Person(s)
Facilities Maintained by the U.S. Department of Agriculture		
Entomopathic Fungi Coll. USDA-ARS Plant Protection Unit U.S. Plant, Soil, and Nutrition Laboratory Tower Road Ithaca, NY 14853-0331 Tel: (607) 255-1276 Fax: (607) 255-2459	ARSEF (PPRU) Telemail: RHUMBER	R. A. Humber, Curator M. L. Cummings, Lab. Tech.
Biological Control of Weeds Laboratory-Europe USDA-ARS American Embassy-AGRIC APO New York, NY 09794-0007 Tel: 011-39-6-507-0140 Fax: 001-39-6-507-0415	BCWLE Telemail: ITALY.FR	L. Knutson, Director
Biological Control of Weeds Research Lab. USDA-ARS Western Regional Res. Ctr. 800 Buchanan St. Albany, CA 94710 Tel: (415) 559-5826 Fax: (415) 559-5777	BCWRL	C. E. Turner, Lead Scientist B. D. Perkins, Q.O.
Beneficial Insects Research Laboratory USDA-ARS 501 South Chapel St. Newark, DE 19713 Tel: (302) 731-7330 Fax: (302) 737-6780	BIRL FTS: 487-6095 Telemail: LC.NEWARK	L. R. Ertle, Q.O. K. S. Swan, Asst. Q.O.
Foreign Disease-Weed Science Research Unit USDA-ARS Fort Detrick, Bldg. 1301 Frederick, MD 21701 Tel: (301) 663-7344 Fax: (301) 663-2880	FDWSRU Telemail: LC.FREDERICK	W. M. Dowler, Res. Leader W. L. Bruckart, Q.O.

Table 1. — Continued.

Laboratory/Address	Acronym/Email	Responsible Person(s)
Insect Quarantine Facility USDA-ARS Grassland, Soil & Water Research Laboratory 808 E. Blackland Rd. Temple, TX 76502 Tel: (817) 774-1201 Fax: (817) 770-6561	GSWRL Telemail: LC.TEMPLE	P. E. Boldt, Q.O.
Hawaii Volcanoes National Park Insect Quarantine Fac. USDA Forest Service 1643 Kilauea Avenue Hilo, HI 96720 Tel: (808) 935-6292 Fax: (808) 935-9801	HVNPIQ	G. P. Markin, Q.O. R. Nagata, Q.O. (training)
Biological Control Lab. USDA-APHIS-PPQ P.O. Box 2140 Mission, TX 78572 Tel: (512) 580-7301 Fax: (512) 580-7300	PPQMTX FTS: 524-0300 Telemail: PPQ.BC.MISSION	L. E. Wendel, Lab. Director P. E. Parker, Q.O.
Stoneville Research Quarantine Facility USDA-ARS Southern Insect Management Laboratory P.O. Box 346 Stoneville, MS 38776 Tel: (601) 686-5282 Fax: (601) 686-9406	SRQF FTS: 497-2282 Telemail: SFC.STONEVILLE	D. D. Hardee, Lab. Director W. W. Harrison, Q.O.
Veterinary Entomology Research Unit USDA-ARS Food Animal Protection Research Laboratory Route 5, Box 810 College Station, TX 77840-9594 Tel: (409) 260-9336 Fax: (409) 260-9377	VTERL	D. L. Bull, Res. Leader G. T. Fincher, Q.O.

Table 1. — Continued.

Laboratory/Address	Acronym/Email	Responsible Person(s)
Facilities Maintained by State Governments and Universities		
Biological Control Lab. Florida Dept. of Agriculture and Consumer Services Div. of Plant Industry 1911 SW 34th Street Gainesville, FL 32608 Tel: (904) 372-3505 Fax: (904) 372-2501	FBCL	H. A. Denmark, Entomol. Bureau Chief C. A. Bennett, Q.O.
Insect Quarantine Lab. Plant Pest Control Branch Hawaii Dept. of Agriculture P.O. Box 22159 Honolulu, HI 96823-2159 Tel: (808) 548-7172 Fax: (808) 548-6100	HDA	K. K. Teramoto, Section Chief P. Conant, Insectary Superv. K. T. Murai, Q.O.
Biological Control Lab. Maryland Dept. of Agric. Plant Protection Section 50 Harry S. Truman Parkway Annapolis, MD 21401 Tel: (301) 841-5920 Fax: (301) 841-5835	MDDA	P. W. Tipping, Q.O.
Insect Quarantine Lab. Entomology Research Lab. Montana State Univ. Bozeman, MT 59717 Tel: (406) 994-4722 Fax: (406) 994-6029	MTSUIQ	F. Dunkel, Dept. Head J. L. Littlefield, Q.O.
Insect Quarantine Facility Biological Control Lab. Plant Protection Section N. Carolina Dept. of Agric. P.O. Box 27647 Raleigh, NC 27611 Tel: (919) 733-6930/2458 Fax: (919) 733-1041	NCDA	R. C. McDonald, B.C. Superv. C. A. Nalepa, Q.O.
	Internet: rmcdonal@mcextc.ces.ncsu.edu	

Table 1. — Continued.

Laboratory/Address	Acronym/Email	Responsible Person(s)
TAMU/TAES Biological Control Quarantine Laboratory Entomology Dept. Texas A&M Univ. College Station, TX 77843-2475 Tel: (409) 845-7938 Fax: (409) 845-7977	TAMU	M. Rose, Q.O.
U. of California Quarantine Div. of Biological Control Univ. of California 1050 San Pablo Ave. Albany, CA 94706 Tel: (415) 642-2198/5989 Fax: (415) 642-0875	UCB	L. K. Etzel J. Hamai, Q.O.
Entomology Quarantine Lab. Dept. of Entomology Univ. of California Davis, CA 95616 Tel: (916) 752-0484 Fax: (916) 752-1537	UCD	L. E. Ehler, Q.O.
Quarantine Laboratory Dept. of Entomology Univ. of California Riverside, CA 92521 Tel: (714) 787-4496 Fax: (714) 787-3086	UCR	G. Gordh, Supervisor S. Warner, Res. Assoc.
Nematode Isolation and Quarantine Facility Dept. of Nematology Univ. of California Riverside, CA 92521 Tel: (714) 787-4431/4432	UCRNQ	P. A. Roberts, Dept. Chair J. G. Baldwin

Table 1. --- Continued.

Laboratory/Address	Acronym/Email	Responsible Person(s)
Minimum Security Greenhouse for Biocontrol of Weeds with Plant Pathogens Plant Pathology Dept. Univ. of Florida 1453 Fifield Hall Gainesville, FL 32611 Tel: (904) 392-7240 Fax: (904) 392-6532	UFGPPD	R. Charudattan
Beneficial Insects Quarantine Lab. Dept. of Entomology Virginia Polytechnic Inst. and State Univ. Blacksburg, VA 24061 Tel: (703) 231-5832 Fax: (703) 231-4163	VPI Bitnet: ENTKOK@VTVM1	L. T. Kok T. J. McAvoy
Planned Facilities		
Biological Control of Weeds Quarantine Lab. Aquatic Plant Management Lab. USDA-ARS 3205 College Avenue Ft. Lauderdale, FL 33314 Tel: (305) 475-0541 Fax: (305) 476-9169	APML	T. D. Center
European Biological Control Laboratory USDA-ARS Montpellier, France	EBCL	L. Knutson
Exotic Pest Research Containment Facility Univ. of California Proposed location unknown	EPRCF	J. M. Lyons (UC) B. L. Callison (CDFA)

Table 1. --- Continued.

Laboratory/Address	Acronym/Email	Responsible Person(s)
Fruit & Vegetable Insects Research Laboratory USDA-ARS Yakima, WA	FVIRL	J. L. Krysan
Plant Pathology Quarantine Facility Hawaii Dept. of Agriculture Honolulu, HI	HDAPPQF	K. K. Teramoto
Beneficial Insects Rearing Facility N.J. Dept. of Agriculture Div. of Plant Industry CN 330 Trenton, NJ 08625 Tel: (609) 530-4193 Fax: (609) 530-4195	NJDA	D. J. Palmer
Biological Control Quarantine Facility USDA-APHIS-PPQ P.O. Box 2140 Mission, TX 78572 Tel: (512) 580-7301 Fax: (512) 580-7300	PPQMTX	L. E. Wendel, Lab. Director P. E. Parker, Q.O.
Citrus Research & Education Center Univ. of Florida - I.F.A.S. Lake Alfred, FL	UFLA	C. W. McCoy H. W. Browning
Tropical Research and Education Center Univ. of Florida - I.F.A.S. 18905 SW 280 Street Homestead, FL 33031 Tel: (305) 246-6340 Fax: (305) 246-7003	UFH	R. M. Baranowski, Center Director H. B. Glenn, Q.O.
	Bitnet: HOM@IFASGNV Internet: HOM@GNV.ifas.ufl.edu	

Table 1. --- Continued.

Laboratory/Address	Acronym/Email	Responsible Person(s)
Insect Disease Quarantine Plant Protection Unit U.S. Plant, Soil, and Nutrition Laboratory USDA-ARS Tower Road Ithaca, NY 14853-0331 Tel: (607) 255-2456 Fax: (607) 255-2459	PPRIDQL Telemail: RCARRUTHERS	R. I. Carruthers, Research Leader T. J. Poprawski, Q.O.

Table 2. Physical characteristics of existing quarantine facilities.

Facility	Location	Size (ft ²)	Other facilities ^a	APHIS Approvals	
				First	Last Inspected
ARSEF	Ithaca, NY	600	None	9/18/79	?
BCWLE	Rome, Italy	1386	GH,IN	N/A	N/A
BCWRL	Albany, CA	2850	GH,LA	/ /86	/ /90
BIRL	Newark, DE	950	GH,IN,LA,RR	11/06/73	2/24/84
FBCL	Gainesville, FL	2544	GH,IN,LA ^b	7/ /73	4/25/88
FDWSRU	Frederick, MD	10000	IN	/ /71	/ /89
GSWRL	Temple, TX	1300	GH,IN,RR	2/10/82	4/03/87
HDA	Honolulu, HI	1150	LA,RR	/ /6?	11/21/90
HVNPIQ	Hilo, HI	600	GH	11/15/84	4/13/89
MDDA	Annapolis, MD	1800	GH	12/ /89	12/ /89
MTSUIQ	Bozeman, MT	1200	GH,RR ^c	7/ /88	7/ /88
NCDA	Raleigh, NC	600	GH,IN,LA	9/06/84	11/27/90
PPQMTX	Mission, TX	1000	IN ^d	5/ /88	5/ /90
SRQF	Stoneville, MS	3400	LA,RR	/ /73	6/11/90
TAMU	College Sta., TX	2000	LA,GH	/ /84	7/ /91
UCB	Albany, CA	646	GH,IN,LA,RR	/ /52	5/07/86
UCD	Davis, CA	90	LA	/ /81	/ /84
UCR	Riverside, CA	570	GH,IN	/ /3?	/ /90
UCRNQ	Riverside, CA	2800	LA	8/ /86	9/ /90
UFGPPD	Gainesville, FL	65	None	/ /71	/ /86
VPI	Blacksburg, VA	1352	IN	/ /72	/ /88
VTERL	College Sta., TX	550	RR	/ /76	?

^a Other (non-quarantine) facilities at location:

GH Greenhouse
IN Insectary
LA Laboratory
RR Rearing rooms and/or incubators

^b Total space now available is 4800 ft²; additional space being built is 3177 ft² (to include 2781 in quarantine).

^c Additional greenhouse bays are to be constructed, and a plant/insect pathogen quarantine facility is planned (construction expected no earlier than 1994).

^d Additional 6000 ft² quarantine space being constructed. See Table 5.

Table 3. Mission organisms, taxonomic sources, and reporting for existing quarantine facilities

Facility	Mission Organisms ^a	Taxonomic Ident. Sources ^b	Reporting Frequency	Report Availability ^c
ARSEF	AP	INH	Biannual	On request
BCWLE	WI	SEL	Annual	On request
BCWRL	WI	SEL	None	
BIRL	AA	SEL,AGC	Annual	On request
FBCL	AA,WI	INH,USNM,SEL	Annual	On request
FDWSRU	WP	INH,SBML,ATCC	Quart., Annual	Limited Distn.
GSWRL	WI	SEL	Annual	On request
HDA	AA,WI	SEL	Monthly	On request
HVNPIQ	AA,WI	HIDA,BISM,UH	Annual	On request
MDDA	AA,WI	SEL	Annual	Not Available
MTSU	WI	SEL	Annual	On request
NCDA	AA	INH,SEL	Annual	On request
PPQMTX	AA,WI	SEL	Weekly	On request
SRQF	AA,PPO	SEL,AGC	Monthly, Annual	On request
TAMU	AA	INH,USNM,SEL,BM,HU	Annual	Through APHIS
UCB	AA,WI	INH	Biannual	On request
UCD	AA	INH	Annual	Through APHIS
UCR	AA	INH,SEL	Biannual	On request
UCRNQ	PPO	INH	Variable	Through CDFA
UFGPPD	WP	INH,ATCC,CBS	None	
VPI	WI	SEL	None	
VTERL	AA	UF,BM	Annual	On request

^a Mission organisms:

AA	Arthropod parasites/parasitoids and predators of Arthropods
AN	Arthropod-parasitic Nematodes
AP	Arthropod Pathogens
PPO	Plant Pest Organisms
WI	Weed-feeding Invertebrates
WP	Weed Pathogens

^b Taxonomic Services:

AGC	Agriculture Canada
ATCC	American Type Culture Collection
BISM	Bishop Museum
BM	British Museum
CBS	Centraal Bureau voor Schimmelcultures
HU	Hebrew University
INH	Inhouse
SBML	ARS Systematic Botany and Mycology Laboratory
SEL	ARS Systematic Entomology Laboratory
UF	University of Florida
UH	University of Hawaii
USNM	U.S. National Museum

^c Most reports are provided to BCDC.

Table 4. Statistics on activity for existing quarantine facilities

Facility	% Activity		Shipments/year		% Cap. used	Scientists served ^a		Pass Thru?
	Res.	Serv.	In	Out		Out	In	
ARSEF	60	40	80	110	90	75	20	Y
BCWLE	50	50	10	40	100	7	3	Y
BCWRL	80	20	25	22	70	10	2	Y
BIRL	25	75	137	279	10-100	23	57	Y
FBCL	85	15	65	40	100	6	8	Y
FDWSRU	95	5	100-150	<5	100	0	2	Y
GSWRL	90	10	40	10	90	5	2	Y
HDA	0	100	13	11	--	0	9	Y
HVNPIQ	0	100	6	2	110	?	2	Y
MDDA	95	5	4	4	30	1	1	Y
MTSUIQ	60	40	35	44	95	0	3-4	Y
NCDA	90	10	4	2	10	-	-	Y
PPQMTX	10	90	65	84	60-70	10	5	Y
SRQF	35	65	22	63	75	5	3	Y
TAMU	100	0	100	?	100	0	5	-
UCB	100	0	8	11	50	1	4	Y
UCD	80	20	5	5	90	2	1	Y
UCR	95	5	61	--	60-90+	0	8	Y
UCRNQ	100	0	3	0	20	0	3	Y
UFGPPD	100	0	0	0	10	0	1	N
VPI	95	5	2	10	80	10	2	Y
VTERL	100	0	2-3	2-3	--	1	1	N

^a Number of scientists served outside facility and inhouse

Table 5. Status of planned and proposed quarantine facilities

Facility	Location	Status
APML	Ft. Lauderdale, FL	In planning & design phase; construction to begin April 1992.
EBCL	Montpellier, France	Construction to be completed by September 1991.
EPRCF	California	Needs feasibility studies; to be completed by January 1992.
FVIRL	Yakima, WA	Construction to begin in April 1992.
HDAPPQF	Honolulu, HI	To receive final APHIS approval in July 1991.
NJDA	Trenton, NJ	Facilities complete; facility not operating currently.
PPQMTX	Mission, TX	Construction to be completed in 1992.
UFH	Homestead, FL	Construction to be completed by early 1991.
UFLA	Lake Alfred, FL	Construction to begin in 1992 or 1993.
PPRIDQL	Ithaca, NY	Construction to be completed in 1992.

Chapter IV. Reports of Working Sessions

Biological Control Quarantine Needs in the United States

Facility Needs: Geographic and Type Organism Considerations

Group 1. Arthropod Parasites/Parasitoids and Predators of Arthropod Pests of Plants, and Arthropod Parasites/Parasitoids, Predators, and Competitors of Arthropod Pests of Humans and Livestock

R. W. Fuester, Chair

The overall capacity of currently certified facilities is good, but they are deployed somewhat unevenly with gaps in service to the North Central States and the Pacific Northwest. Construction and certification of the planned facilities in Yakima, Washington; St. Paul, Minnesota; or Niles, Michigan, would alleviate the situation as would recertification of the facility at Columbia, Missouri.

Costs of quarantine construction are quite high (ca. \$500 per ft² for full containment), so an alternative solution to meeting projected increases in natural enemy importations would involve the substitution for proposed new primary facilities of secondary quarantines that could accept pure cultures of Class C candidate biological control agents (see Appendix 3, Guidelines for Arthropod Natural Enemies of Arthropods, Sections V.A.2 and V.A.4). In order for this to work, the workload at existing primary quarantine facilities currently in operation would have to be evened out. Most units process fewer than 25 incoming shipments per year while a few (mostly federal) process over 150 shipments per year. The rerouting of shipments needed to even out the workload at high volume facilities is primarily a federal problem, but the possibility of using state facilities to alleviate the problem should not be precluded.

Group 2. Arthropod-parasitic Nematodes

W. R. Nickle, Chair

No additional containment/quarantine facilities for arthropod-parasitic nematodes are deemed necessary. (See pertinent proposed Guidelines in Appendix 3.)

Group 3. Invertebrate Natural Enemies of Weeds

P. C. Quimby, Chair

Additional quarantine facilities are needed in Raleigh, North Carolina, and Beltsville, Maryland. Another foreign screening facility is needed in Hurlingham, Argentina.

One current problem is obtaining research plants from other areas. Another is that, without a quarantine facility in an area, it is impossible to send personnel, plants, and other materials for testing because of financial considerations.

Quarantine units are needed to serve different vegetational regions and/or weed regions. Presently, most quarantine facilities are seasonal:

Albany, California, is used 100%.

Regina, Canada, has no quarantine greenhouse.

Bozeman, Montana, is under-utilized, with heavy usage seasonally.

Temple, Texas, is filled in winter and spring.

Blacksburg, Virginia, is under-utilized.

Mission, Texas, is at 50% capacity now. It is primarily a pass-through facility.

Annapolis, Maryland, is under-utilized.

Gainesville, Florida, is at 100% now. A new facility will reduce this to about 80%.

Stoneville, Mississippi, is under-utilized.

Hilo, Hawaii, is 110%; expansion is needed and planned.

Whiteville, North Carolina, does no biological control work, just weed seed.

Areas not served include southern Florida, Puerto Rico, and Mexico.

Needs of the quarantine facilities are as follows:

Albany: personnel.

Regina: to separate insects group from pathogen group.

Bozeman: expansion of space, personnel, finances.

Temple: funding, equipment, space.

Blacksburg: okay.

Mission: okay.

Annapolis: personnel.

Gainesville: refurbishing, personnel.

Stoneville: (no representative to report on conditions).

Hilo: (undergoing expansion).

Whiteville: personnel, facility may be terminated in 1995.

In summary, quarantine needs could be met if sufficient personnel were available, if the tropical region is addressed, and if the facility in Argentina is refurbished to contain and grow introduced plants. There is a need for coordination to address facility needs.

Group 4. Microbial Pathogens of Arthropods

R. A. Humber, Chair

There was no feeling that there is any major need for additional quarantine facilities to deal with microbial pathogens of arthropods. There is an adequate number and geographical distribution of laboratories treating the entire range of entomopathogenic microbes. It is encouraging that new facilities currently being completed at American Cyanamid (Princeton, New Jersey) will be Biosafety Level 3 (BL-3) quarantine facilities specifically designed for work with entomopathogenic microbes; it is intended to make these facilities available for cooperative use by the State of New Jersey and by invertebrate pathologists. A new quarantine facility being constructed in Gainesville by the State of Florida may have one of its seven rooms designated for operations in quarantine involving pathogens.

Guidelines for arthropod quarantine facilities indicate that pathogens found in incoming shipments should be destroyed. This policy suggests a fundamental conflict of interest in intentional introductions of entomopathogens to quarantine facilities devoted to arthropods. This conflict might be more troublesome for insect pathologists if there were a substantial need for studies of microbial pathogens together with populations of quarantined insect hosts.

It should be noted, however, that there was common agreement that facilities dealing with microbial entomopathogens should be regarded as containment facilities rather than quarantine facilities in the strict sense applied to facilities for insect predators and parasites. The presence of biological safety cabinets Class II (Type A), ready access to an autoclave, ready decontamination of a facility, and strict observation of good microbiological technique characterize nearly all U.S. labs dealing with microbial entomopathogens; depending on the design of any given laboratory, most of these would be found to meet at least minimal qualifications for classification as BL-2 facilities according to CDC Guidelines. Such

facilities are agreed to be fully adequate for work with nearly all naturally-occurring entomopathogenic microbes. Safety precautions and design requirements are much more stringent for research involving genetically-engineered organisms and require BL-3 facilities that could legitimately be regarded to be quarantine facilities.

It was agreed that, to the extent possible, biocontrol facilities using microbial pathogens should be designed to exceed the minimal standards for BL-2 certification. It was suggested that all such facilities be inspected and rated by local Institutional Biotechnology Committees for compliance with CDC and other pertinent guidelines before approaching APHIS for certification of the facility. Certification of a containment facility by APHIS should involve a combination of physical facilities and a comprehensive and adequately detailed set of Standard Operating Procedures, as well as competently-trained scientific and technical staffing. Nobody was disturbed at the thought of linking a facility's rating of acceptability to APHIS with the person in charge so that any substantive change of the facility or its leader should trigger a review of the facility's containment rating.

Group 5. Pathogens of Weeds *W. L. Bruckart, Chair*

(1) Construct facilities for evaluation of weed pathogens overseas. Foreign exploration is fundamental support for evaluation of exotic pathogens of U.S. weeds. Laboratories located overseas provide the optimal support for collection and isolation of weed pathogens. The additional research capabilities from permanent overseas staff would be an important factor in expediting the development of plant pathogens.

(2) Increase capability of weed pathogen containment research/receipt in the U.S. Currently, only 20% of the weed species considered suitable targets for biocontrol at the Weed Biocontrol Workshop in 1984 are being evaluated for biocontrol by plant pathogens. Considering that research in biocontrol of weeds is initiated after all other control strategies have failed, it is very important to expedite the use of plant pathogens for weed control. This can be accomplished by developing additional containment facilities and by staffing present and planned facilities with trained ARS technical and scientific personnel. Specific locations include Frederick, Maryland, and planned state facilities at Honolulu, Hawaii; Bozeman, Montana; and

Fayetteville, Arkansas. An ARS facility should be considered for location at Albany, California, to complement the insect containment research in place. The Albany location is very near international airports and much of the agriculture in the U.S. These facilities can be designated as primary or secondary receiving centers.

(3) Include state-of-the-art approaches to construction and design of containment facilities. These facilities should be state-of-the-art, designed with a perceived purpose and based on efficiency and flexibility. Principal design considerations include capability to handle multiple isolates and options for expansion or modification. Experience with design and construction of containment at Frederick, Maryland, and Honolulu, Hawaii, should be considered, and consultation with APHIS is mandatory.

Group 6. Natural Enemies and Antagonists of Plant Pathogens and Nematodes *G. C. Papavizas, Chair*

We do not anticipate a great volume of importations that will trigger quarantine in plant pathology and nematology. Most of the importations will be in the form of pure cultures in test tubes, small amounts of soils, and dead plant materials and cadavers harboring potential MPCAs. Because of these considerations and of the comments in Chapter 3 above, the members of Group 6 recommend that no separate containment facility be established for plant pathogens and nematodes. It is unrealistic at this time to request a separate physical facility for potential MPCAs of plant pathogens and nematodes. Group 6 recommends that quarantine laboratories be established within existing quarantine facilities for fungi and bacteria, potential biocontrol agents that can be used against diseases caused by bacteria, fungi, and nematodes. If finances permit in the future, Group 6 recommends that one or two existing quarantine facilities be staffed with a mycologist and a bacteriologist. The two scientists should have adequate support for routine laboratory and greenhouse tasks.

Coordination/Communication Needs

Group 1. Arthropod Parasites/Parasitoids and Predators of Arthropod Pests of Plants, and Arthropod Parasites/Parasitoids, Predators, and Competitors of Arthropod Pests of Humans and Livestock

R. W. Fuester, Chair

Coordination/communication needs fall into four categories: (1) those needed to eliminate hassles associated with getting shipments through ports of entry, (2) those needed to provide information on importations between quarantines (one to another) or between quarantines and other biocontrol scientists, (3) those needed to assure proper documentation of natural enemy importations, and (4) uncertainty as to what will be required for approval for field release of biological control agents.

(1) Measures to facilitate importations which might be implemented to eliminate difficulties at ports of entries include the following:

- (a) Providing information on PPQ Form 526 in the Port Operations Manuals issued to port inspectors and customs officials.
- (b) A special 800 number to call when complications arise (e.g., a flight is rescheduled, re-routed, etc.).
- (c) Attaching a copy of PPQ Form 526 to the package.
- (d) Printing special boilerplate on PPQ 526 and Stickers to the effect that "THIS PACKAGE CONTAINS LIVING ORGANISMS FOR BIOLOGICAL CONTROL PURPOSES. IT MAY ONLY BE OPENED IN A PRIMARY QUARANTINE FACILITY."

(2) Measures which would improve coordination and communication within the biological control quarantine community include the following:

- (a) Creation of a Biological Control Quarantine Bulletin Board. One approach might be to have NBCI develop this.
- (b) Promotion of newsletters (e.g., the International Organization for Biological Control (IOBC) Nearctic Regional Section newsletter) might be appropriate.
- (c) Publishing notices of approved PPQ Forms 526 for biological control agents.

(3) Documentation is needed. There was general agreement that a standardized documentation system is needed that would provide information to account for importations that otherwise might not be published, but that would protect researchers from data piracy or other undesirable practices. A national repository for importation and field release records could provide such a service, which could also serve as a back-up for quarantine records. It was recognized that the BCDC was a logical choice to fulfill this need.

Therefore, it was recommended that BCDC be supported in an effort to develop such a system. Points to be considered in system development included the following: a task force to determine those elements of data that should be compiled, provision for electronic submission of data from remote locations, provision for direct access and query by modem, and provision of sufficient clerical and data processing resources to make such a system work.

(4) There is uncertainty as to what will be required for approval for field release of biological control agents. Because of problems or perceived problems with the approval process, particularly those foreseen in the future, there is a need for APHIS, as the permitting agency, to provide the biocontrol community with an idea of what is likely to be needed to obtain field releases of arthropod parasites, predators, and competitors in the near future. Those areas causing the greatest concern were probable time delays, the probability of a categorical exclusion for certain types of natural enemies, a fear that the overall safety record with these types of organisms would not be considered, the relative weighting of scientific data versus public perceptions, a mechanism for continued dialogue, and the feasibility of NBCI's serving as an interface between the biocontrol community and APHIS BBEP.

Group 2. Arthropod-parasitic Nematodes

W. R. Nickle, Chair

The Society for Nematologists and Cooperative State Research Service (CSRS) regional projects such as SR-240, which deals with microbial biocontrol including nematodes, provide satisfactory vehicles for exchange of information and coordination of research among federal, state, and commercial laboratories.

Group 3. Invertebrate Natural Enemies of Weeds

P. C. Quimby, Chair

(1) The Group members listed needs as follows:

- (a) Coordination of work and shipments of quarantine facilities.
- (b) Utilization of under-utilized facilities.
- (c) Exchange of ideas.
- (d) Standardization of quarantine officer activities, including training.
- (e) Daily communication.
- (f) Communication of receipt of a shipment.
- (g) Notification of best shipping carriers and shipping time.
- (h) Communication with the port of entry.
- (i) Exchange of paperwork between foreign and state laboratories.
- (j) Communication with the user groups on space availability and organisms worked on.
- (k) Coordination of plans and programs.
- (l) Pooling of resources.
- (m) Newsletter relating "who is doing what".
- (n) Availability of agents, sharing of material.

(2) The Group makes the following recommendations:

- (a) An electronic biological control bulletin board should be developed. NBCI should be the main broker of information.
- (b) Researchers should express need for space.
- (c) Notices should be placed in the IOBC Newsletter.
- (d) Short course in quarantine procedures should be included in certification of the facility. Standard Operating Procedures should be developed and periodic workshops held. All of these can probably be supplied by NBCI.
- (e) Airway bill number, flight number, air carrier, Port of Entry, and contact telephone number should be communicated for a shipment. All should be sent by Fax.
- (f) At the Port of Entry, quarantine personnel should coordinate with the PPQ officer before arrival and communicate with agricultural inspection and customs. The permit number should be in network from the permit section, along with the customs section. New colored permit labels should be used.

(g) The Fax number should be placed on the shipment form, and information that the shipment arrived and in what shape it arrived should be sent promptly. This is needed as soon as possible for use in the next shipment.

The Group strongly supports Norman Leppla by recommending that the NBCI be completed and a communications system be made available as soon as possible.

Group 4. Microbial Pathogens of Arthropods

R. A. Humber, Chair

The Society for Invertebrate Pathology, CSRS, and regional projects such as SR-240 (which deals with microbial biocontrol) provide excellent vehicles for the frequent and detailed exchange of information among laboratories studying microbial pathogens of arthropods and for the effective coordination of national research efforts among federal, state, and commercial laboratories.

There is a need for a higher level of compliance with regulatory requirements for the importation and interstate movements of microbial pathogens of arthropods, and for providing needed information on the movements of biological control organisms into the U.S. and, with APHIS permission, out of containment into open field sites. Some existing misunderstandings regarding requirements to obtain APHIS authorization for the movement of microbial biocontrol agents can be clarified by a more concerted educational effort among affected scientists (e.g., through CSRS programs, SR-240 meetings, and meetings in scientific societies, etc.). There is also a real need to educate the scientific community about the existence and requirements of agencies in many states that regulate the movements of living organisms. These state regulatory bodies usually operate in parallel with federal regulatory authorities, but some impose more stringent constraints than their federal equivalents.

There is a generally-perceived need to facilitate the filing of required documentation of shipments and releases of biocontrol organisms to the BCDC by developing means for electronic submission of these data. There should be a greater effort to publicize the ROBO database and to expand general access of the scientific community to the information in this database.

Group 5. Pathogens of Weeds *W. L. Bruckart, Chair*

(1) Documentation of biological control activities should be made more accessible to users. The use of computer technology facilitates interaction between scientists and databases. The ROBO database at the BCDC does not use commonly-available computer software. If data at the BCDC were made available on commonly-used software or in an IBM (or Macintosh) compatible format, it would be much more accessible to scientists for data entry and retrieval.

(2) Activities for quarantine/containment between biological control quarantine and containment facilities must be better coordinated. Function of various weed biocontrol operations (present and planned) will be more efficient if the role and contribution of each is clearly defined and staffing at each facility reflects the role. This includes the potential research and redistribution of pathogens from overseas facilities in France and China and in designated pass-through and receiving facilities. A much greater volume of acquisitions could be handled in this way, and there is the possibility for a significant increase in the volume of shipments if the overseas facility is developed and interest in weed pathogens continues to grow.

(3) Procedures for review of targets and for release of biological control agents must be improved. Presently, interagency review of proposals for planned research and for release of exotic weed pathogens is adequate through the TAG. However, there are no individuals with expertise in plant pathology on the TAG, and review by TAG of proposals for release of weed pathogens may be inadequate. We recommend in-house expertise at APHIS for review of proposals to release weed pathogens. Also, APHIS should have capability to set up science advisory panels for cases that require more particular considerations.

(4) Training programs must be developed for quarantine officers and scientists. Individuals with responsibility as quarantine officers need to understand what this entails. There are a number of procedures, forms, and other activities for operation of a containment facility that quarantine officers and scientists working in containment need to know.

Group 6. Natural Enemies and Antagonists of Plant Pathogens and Nematodes *G. C. Papavizas, Chair*

Coordination Because of many uncertainties with reference to needs for quarantine facilities in plant pathology and nematology, Group 6 was unable to reach any meaningful suggestions on how quarantine laboratories in existing quarantine facilities can be coordinated. We believe that the ARS National Program Staff should find an acceptable way of coordination when and if such quarantine laboratories can be established for MPCAs of plant pathogens and nematodes.

Communications The Biocontrol Committee of the American Phytopathological Society publishes a biannual biocontrol newsletter which can be used to communicate quarantine biocontrol news. Group 6 also recommends that a firm and workable communication system be established between ARS and CSRS.

Taxonomic Research and Service Needs

Group 1. Arthropod Parasites/Parasitoids and Predators of Arthropod Pests of Plants, and Arthropod Parasites/Parasitoids, Predators, and Competitors of Arthropod Pests of Humans and Livestock *R. W. Fuester, Chair*

There was unanimous agreement that taxonomic research and identification services are key components of the national biological control effort. Importation of exotic natural enemies simply cannot proceed without a knowledge of what organism one is dealing with. Several recommendations were made with relation to taxonomic research and services. One point made was that the involvement of systematists should be sought out early on in the project planning process. In addition to identifying material, taxonomists can offer suggestions on host plant distributions, ancestral homes or probable autochthonous distributions of target pests, degrees of host specificity likely to occur in various natural enemy taxa, and other pertinent information. Because of the importance of authoritative identifications to biocontrol work, Group 1 felt it was appropriate to go on record as expressing a desire to see increased support for research in arthropod systematics, particularly in regards to maintaining institu-

tional and technical support. Research areas cited as being in special need of attention were neotropical fauna, the genus *Aphidius*, and interdisciplinary studies combining molecular and morphological approaches.

Voucher Specimens Because of the need for a more standardized policy for voucher specimens (q.v., Appendix 3, Guidelines for Arthropod Natural Enemies of Arthropods, Section V.E) and the recognition that there are finite limits to the numbers of voucher specimens that can be stored in recognized collections, it was recommended that a task force be convened to make recommendations concerning overall policy. Important issues to be discussed include the following: (1) What is important enough to save, and what is not? (2) Designation of a uniform color for voucher specimen labels. (3) Review of the requirement that voucher specimens of organisms approved for release (PPQ Form 526) must be placed in a specific institution. (4) The feasibility of establishing a national repository for voucher specimens. The ability of the ARS SEL to handle the last task at current levels of support is problematic.

Group 2. Arthropod-parasitic Nematodes *W. R. Nickle, Chair*

Much increased taxonomic research efforts on arthropod-parasitic nematodes are needed. There are currently only five scientists devoted only part-time to research in this area in the U.S.

Group 3. Invertebrate Natural Enemies of Weeds

P. C. Quimby, Chair

(1) The Group listed the following needs with regard to plant taxonomy:

(a) A list of plants that are major problems includes knapweeds, spurges, houndstongue, Canada thistle and other thistle species, chamomile, saltcedar, and salvinia. There is a definite need for a list of plant taxonomy specialists.

(b) More research is needed in the following areas:

Origin (biogeography)

Classification of subspecies levels

Center of species versus origin

New approaches, including DNA techniques and other biochemical methods

Screening work

The question whether biological variation is less or more than the taxonomic variation.

(c) Support for overseas research on biogeography and overseas cooperation between biological control workers and taxonomists.

(d) Knowing who can do what in overseas laboratories.

(e) Taxonomists should be part of the research team, especially prior to the initiation of the biological control project.

(2) Group 3 listed the following needs with regard to insect taxonomy:

(a) Many groups have little taxonomic expertise and many of the groups are complexes (including Lepidoptera, especially Microlepidoptera, chironomids, cecidomyiids, Homoptera, thrips, leafhoppers, weevils, Apions).

(b) Support of the systematists.

(c) Identifications of foreign insects, which are difficult to obtain.

(d) A list of names of taxonomy specialists. (First for North America and then for the world.)

(e) Screening tests often reveal differences in taxonomic groups.

(f) Voucher specimens for both insects and plants.

(g) More knowledge of the biology of the species.

(h) Consistent requirement of voucher specimens (e.g., PL 480 projects' lack of voucher specimens being provided to the national museum.)

We need to involve the taxonomist from the beginning of the project. Can the overseas laboratories provide vouchers to the National Museum? Some of the taxonomist's needs for publication can be served if he/she is part of the team. The SEL has received funds from Congress for a Category IV service scientist (i.e., with responsibility for identification; up to 20% research and the rest as service.) They do now have a beetle person. Their goal is to keep research joined with service to keep their scientists current.

The group supports the following ideas: Taxonomists need to receive and provide specimens, especially with sibling and related species from the researcher. British taxonomists should be used when appropriate. Note that Phil Lima will accept identifications from the British Museum.

In summary, many plant and insect fields need taxonomic research to support biological control. Taxonomists need to be part of the team, and there should be joint publications and funding support. Biogeographic research is also needed. New approaches to taxonomy and the hiring of new scientists should be promoted as needed. We need lists of specialists of plant and insect taxonomists.

Group 4. Microbial Pathogens of Arthropods

R. A. Humber, Chair

Fungi Complete identification services for fungal pathogens of invertebrates are available from R. Humber (ARS Plant Protection Research Unit, Ithaca, New York). This service and taxonomic research on these fungi is supported by the ARS Collection of Entomopathogenic Fungi (ARSEF) comprising more than 3,000 isolates of more than 200 fungal taxa, and an officially registered herbarium (also bearing the ARSEF designation) for specimens of entomogenous fungi. Taxonomic research focuses on fungal entomopathogens in the Entomophthorales (Zygomycetes) and conidial fungi in the Hyphomycetes. There is a great deal of literature dealing with the systematics of entomopathogenic fungi, but the state of taxonomy in the great majority of fungal genera is relatively primitive and still dependent upon morphologically-based systematics.

Microsporidia At least four U.S. laboratories are currently involved with long-term research programs on the systematics and biology of microsporidians. These

scientists are T. Andreadis (Connecticut Agricultural Research Station, New Haven, Connecticut), J. Becnel (ARS Medical and Veterinary Entomology Research Laboratory, Gainesville, Florida), Wayne Brooks (North Carolina State University, Raleigh, North Carolina), and J. Maddox (Illinois Natural History Survey, Champaign, Illinois). These laboratories are competent to cover most of the identification needs for these pathogens within the U.S. The systematics of the microsporidia is unsettled and in great need of revisions that incorporate very recent discoveries about the life cycles of these organisms that might potentially lead to the consolidation or reassignment of many taxa.

Bacteria Studies on entomopathogenic bacteria focus primarily on approximately four serotypes of *Bacillus thuringiensis* (*B.t.*). Commercial products are available in the U.S. from several different firms, each of which maintains extensive proprietary collections and research programs using naturally occurring, induced sexual recombinants, and genetically-engineered material. The major ARS effort involving *B.t.* is led by P. Martin at the Insect Pathology Laboratory (Beltsville, Maryland); this effort has focused on the isolation and characterization of this bacterium from soil and other substrates collected in many geographically diverse sites. The most important functional taxonomic designation for *B.t.* strains is the serotype (although this need not be determined for any but relatively few important strains) since varieties are defined according to their serotypic characterization; laboratories in France and Japan are the only ones where all serotypes can be determined. Other significant studies involving entomopathogenic bacteria focus on *Bacillus popilliae*, the causative agent of milky spore disease of turf-dwelling scarabaeids; the major U.S. research on this bacterium is led by M. Klein (ARS Application Technology Research, Wooster, Ohio). No U.S. programs studying entomophilic bacteria have substantial commitments to systematic bacteriology; except for the needs to determine serotypes for *B.t.*, needs for systematic bacteriology seem to be well met by the information available in the classic reference manual for this discipline, *Bergey's Manual of Determinative Bacteriology*.

Rickettsia and Mollicutes It was not felt that there is any significant effort in the U.S. to study the basic biology of these organisms or to develop them for effective biological control. There is, effectively, only a single laboratory focussing on these organisms.

Viruses Numerous federal, state, and commercial laboratories in the U.S. pursue intensive and long-term research programs on the biology of entomopathogenic viruses. None of the U.S. labs is specifically concerned with viral systematics although many of the labs are able to do standard biochemical and genetic characterization of entomopathogenic viruses. Identifications of viruses usually need not be pursued to a level below that of the family (which is relatively easily determined). Neither, however, is it generally agreed how viruses can be appropriately classified to taxa below this level. Most work on entomopathogenic viruses is restricted to the baculoviruses (i.e., nuclear polyhedrosis viruses, cytoplasmic polyhedrosis viruses, and granulosis viruses). Most studies on these insect viruses focus on a very small number of well-characterized viruses. At the present time, there is relatively little unfulfilled need for identification or other services involving entomopathogenic viruses in the U.S.

Group 5. Pathogens of Weeds *W. L. Bruckart, Chair*

(1) A list of recognized experts needs to be developed for systematic services. Certification of experts through an appropriate scientific society also may be useful. Such an arrangement would provide weight to identifications, since the list (or certification) would represent endorsement by qualified peers. Identifications provided by recognized systematists would lend legal as well as scientific credibility.

(2) Support must be insured for classical as well as molecular taxonomic research. Mechanisms for support need to be developed for research in the taxonomy of fungal, bacterial, and viral plant pathogens. All genera of plant pathogens are in need of research and study. Understanding the taxonomic relationships within a genus or group of plant pathogens enables more rapid, confident identifications of specimens of interest in the future. It is important to maintain the classical approaches to identification, since the first grouping of any organism is based upon morphological features. Among the possibilities are fee-for-services and line item entries for taxonomic identifications in proposals.

(3) Voucher specimens should be required before proposal to release is made. Development of microorganisms for biocontrol of weeds, insects, or other pests involves

breaking new ground. Most pests are not well studied in terms of their natural enemies, so little is understood about the microorganisms that attack them. New taxa or changes in current taxa are very likely to be made because of this dearth of information. Voucher specimens provide a permanent record of what has been studied, and they provide a reference point that can be checked when changes in taxonomy are made. To require them for submission of a proposal insures this important scientific action is taken.

Group 6. Natural Enemies and Antagonists of Plant Pathogens and Nematodes *G. C. Papavizas, Chair*

Taxonomic expertise is badly needed in plant pathology and nematology to identify fungi and bacteria that can be tested as potential MPCAs. ARS has hired only one taxonomic mycologist assigned to perform research on biosystematics of *Trichoderma* and *Gliocladium*, two important biocontrol agents. There is a complete void on the taxonomy of other fungi and bacteria for both, quarantine and research purposes. Group 6 recommends that every effort be made in the next few years to obtain funds (i.e., new funds or funds from redirections) to hire two taxonomic mycologists and a bacteriologist to assist other researchers on research and quarantine matters.

General Biological Control Quarantine Procedural Needs

Group 1. Arthropod Parasites/Parasitoids and Predators of Arthropod Pests of Plants, and Arthropod Parasites/Parasitoids, Predators, and Competitors of Arthropod Pests of Humans and Livestock *R. W. Fuester, Chair*

The Group discussed the draft ARS Guidelines for parasites and predators in detail, and the resulting redraft with subsequent emendations appears in Appendix 3, A.

Group 2. Arthropod-parasitic Nematodes *W. R. Nickle, Chair*

The Group discussed the draft ARS Guidelines for arthropod-parasitic nematodes in detail, and the resulting redraft with subsequent emendations appears in Appendix 3, B.

Group 3. Invertebrate Natural Enemies of Weeds *P. C. Quimby, Chair*

The draft ARS Guidelines for invertebrate natural enemies of weeds were not discussed in detail during the session. However, a revision of the early draft was submitted later and appears, with additional emendations, in Appendix 3, C.

A lively discussion developed with respect to the suggested Biological Control Advisory Committee (BCAC) to augment the current TAG. The purpose of the BCAC would be to advise PPQ on technical questions about the introduction and release of natural enemies of target weeds. The BCAC would be very similar to the "Agent Review Group" suggested by Peter Harris of Agriculture Canada in his address to this workshop (q.v., Appendix 2). According to this suggestion, the TAG would continue to have responsibility for decisions regarding the suitability of target weed selection and would provide advice on plants to be included in host specificity tests to satisfy concerns about endangered/threatened plant species, native plants related to the proposed target(s), and economic/ornamental plants of concern.

Since no consensus could be reached on the question of establishing a BCAC, a parliamentary solution was sought, and it was moved and seconded that the BCAC be added to review biological control agents, and that TAG would be restricted to approving potential weed targets. The motion failed 8 to 5 with 7 abstentions. An alternative motion was offered and seconded, viz. "to keep the TAG in its present configuration and the chairman of TAG should continue to use and emphasize the use of specialized scientific expertise in providing information for decisions." This motion passed overwhelmingly (18 to 1).

Then a discussion ensued about public notification of proposed weed targets. The sense of the group was to approve the concept of public notification of PPQ action

on TAG recommendations with regard to candidate target weeds. It was recognized that procedures for this public involvement would have to be developed if PPQ decides to accept and implement this suggestion. Several members pointed out that individual proponents of biological control projects on target weeds could publicize those proposals.

According to Phil Lima of APHIS PPQ, the TAG provides advice regarding the following:

- (1) Endangered/threatened species (concern of the U.S. Fish & Wildlife Service).
- (2) Native species related to target weeds (concern of the National Park Service).
- (3) Conflicts of interest.
- (4) Host specificity, including economic crops and ornamentals of concern.

The next issue discussed was the existing need for a uniform policy on the elimination of mites, microbial pathogens, and nematodes from the beneficial weed-feeding arthropods. It was concluded that a suggested policy needed to be formulated and circulated to all biological control researchers working with arthropods for review. Paul Parker of APHIS PPQ agreed to take the lead on that project.

George Markin of the USDA Forest Service suggested that the proposed guidelines are too provincial; that is, they are too focused on problem weeds and their natural enemies originating in Western Europe. He would like to see the guidelines more flexible on research allowed in quarantine with respect of weeds and agents from South America and Africa, where it is difficult to do much research in the countries of origin.

The level of host range screening and rearing permitted in quarantine should be determined on biological and administrative realities on a case by case basis. Examples were cited of various needs in this regard, such as the need to test native plants in the U.S.

One request was expressed that a document be produced that provides detailed information on how to construct various types of quarantines for different organisms. The

participants would like to ask J. W. Smith of Rhone-Poulenc Agriculture Company, who has pulled much of this material together, to prepare such a document and make it available for general use.

Concern was expressed that some policy needs to be developed for researchers of natural enemies of arthropod pests to consider the host range of "beneficial" imported parasites to be sure that they will not attack "beneficial" weed-feeding arthropods.

Two related concerns were that the guidelines need to include procedures to ensure that the germplasm (i.e., any group of biological control agents) being brought in is free of natural enemies before release and that the source of germplasm that underwent host-range testing should be the source of the germplasm released.

All participants agreed that we should all spend more effort on emphasizing the positive benefits of biological control.

Some consideration needs to be given to occasional cases when it might be appropriate to conduct host-range testing in countries where biological control agents have already been released or on islands where escapes would perish.

Jack Coulson noted that the proposed guidelines and possible directive will be revised further and provided for review by all concerned. He emphasized that it should be a dynamic document and will be constantly updated as needed. The participants appreciated the tremendous effort and work put into these documents by Jack Coulson and his devotion and contributions to biological control over the years through the ARS BCDC.

Group 4. Microbial Pathogens of Arthropods

R. A. Humber, Chair

The revised ARS Guidelines for microbial pathogens of arthropods resulting from this session appear, with additional emendations, in Appendix 3, D. The following additional comments were developed at the session.

Importation considerations

Approvals and permits It was hoped that APHIS would be willing to issue blanket permits for the importation of an appropriate range of organisms to any APHIS-certified facility meeting or exceeding the requirements for BL-2. Any such blanket permits should be subject to review and renewal every two years, and will require submission of periodic reports providing pertinent information about all importations under this permit.

Shipping/routing problems There do not seem to be any substantial problems here for microbial pathogens of arthropods. Most exotic microbial pathogens of arthropods are entering the U.S. as pure cultures or in fresh cadavers of the host. Most of these shipments arrive at the receiving laboratories from even rather remote parts of the world with the pathogen in viable and perfectly acceptable condition. Instances when such pathogens must enter the U.S. in living hosts are relatively rare and can be adequately handled through existing regulatory permitting processes. The only question that might be raised about passing imported shipments through a small network of certified containment receiving facilities (as is proposed in the Guidelines) is the handling and disposition material that is being imported under agreements of confidentiality due to involvements at either the shipping or receiving end with potential patent considerations.

Quarantine receipt and handling considerations

Basic risks involved and specific containment facility needs It is perceived by invertebrate pathologists that there is little basic risk in receiving and handling microbial pathogens of arthropods. Most of these organisms are moved among laboratories as pure cultures or as infected cadavers. In either instance, safe containment and handling of these organisms has proven in nearly every instance to require no more "quarantine" facility than good microbiological technique exercised in a vertical flow biological cabinet (Class II, Type A). Arthropod pathogens have little dispersive power in comparison to that of most live arthropods. Even if large quantities of microbes were somehow dispersed into the air, most microbial pathogens would characteristically be inactivated rapidly by desiccation, by exposure to UV irradiation (in open field conditions), or by other physical conditions encountered during the accidental release. Most arthropod pathogens characteristically have narrow

host ranges (often being confined to a single genus or family of hosts) and are unable to survive long in the absence of a suitable host.

The safety of very nearly all invertebrate pathogens for humans and other vertebrates is well established. Most of the viruses, bacteria, fungi, and microsporidia that attack insects or other arthropods are incapable of establishing infections in healthy vertebrates. The considerable recent increase in the number of immunologically-comprised humans--whether due to the effects of immunodeficiency viruses, the increasingly "routine" replacement of human organs by transplantation, or the responsible use of many common prescription and over-the-counter medicines, or by the effects of the abuse of alcohol and other drugs--leaves increasing numbers of individuals susceptible to facultative infections by organisms that have never been noted to cause medical problems, and all laboratories handling microbes should be aware of this arising problem. On a much more benign note, substantial exposure to fungi, bacteria, or other microbes may lead to the development of hypersensitive (allergic) reactions. The protection afforded by routinely handling microbial pathogens of arthropods in appropriate biological containment cabinets to the greatest extent possible goes far to assure that such hypersensitization will remain unlikely among laboratory workers.

Quarantine personnel and Standard Operating

Procedures (1) Quarantine officer duties and training, and quarantine uses by other personnel. Containment (or Quarantine) Officers should be well trained in general principles of organismal containment and microbiology. There is no perceived need for more specialized training programs beyond this basic level for Containment Officers in charge of BL-2 facilities, although periodic meeting with any working group or ad hoc workshops for quarantine and containment officers is advisable in order to keep abreast of ongoing concerns and new advances in the state of the art. Quarantine (or Containment) Officers in charge of BL-3 facilities for microbial pathogens (especially those involving the creation and/or handling of genetically-modified organisms) should probably undergo some degree of apprenticeship or consultation with one or more quarantine officers in charge of arthropod quarantine facilities, and are strongly advised to maintain working relationships with other quarantine officers through any periodic training courses or workshops given for such personnel. Officers in charge of facilities in which geneti-

cally-modified organisms are handled should strive to maintain an up-to-date understanding of all pertinent safety issues and federal guidelines about the measures needed to maintain containment of such organisms and their genomic derivatives.

(2) Quarantine Operating Procedures. A Standard Operating Procedure should be established in all biological control facilities in order to enumerate all general operating conditions for that facility. Very few laboratories dealing with arthropod-pathogenic microbes currently have such Guidelines. Models for such documents can be obtained from the ARS Medical and Veterinary Entomology Research Laboratory (Gainesville, Florida) or from the ARS BCDC.

(3) Processing incoming material. Unsolicited shipments should be opened and inspected. If live insect material is included, the shipment should be processed and, as needed, ex post facto application to APHIS should be made on an informational basis using any available collection information included with the shipment; the material should be retained for possible destruction of the lot if so ordered by APHIS. The shipment should be destroyed if it includes living insect material. Packages should be opened in the Class II, Type A, biological containment cabinet, preferably fitted with a glove-fitted face plate that completely encloses the area inside the cabinet. Packaging material should be autoclaved or incinerated after opening.

(4) Taxonomic problems and procedures. Most recognized receiving laboratories have in-house expertise for the identification of the arthropod pathogens that they handle. The degree of taxonomic expertise needed varies according to the organisms. Fungi and microsporidia are often identifiable to the species level; viruses and bacteria may not need such a precise determination. All receiving facilities should be alert to the possible receipt in shipments of potentially detrimental microbes (e.g., anthrax bacilli, arboviruses, etc.) needing immediate destruction and subsequent decontamination of the receiving facility.

(5) Host specificity and other tests. Such work is often not a routine part of work with microbial pathogens of arthropods. Much work to establish host ranges is usually done at containment facilities other than those of the original receiving lab. The biology of most microbial pathogens of arthropods is well enough understood to

know that they might be safely shipped from one microbiological containment facility to another. It is well understood among insect pathologists that it is often extraordinarily difficult to induce disease outbreaks at will and that such outbreaks are almost unknown as a result of accidental dispersal of a pathogen. Only rarely may an unidentified microbe present any risk that would require study of its host range before release from the original receiving facility to any other similarly equipped microbiology laboratory facility.

(6) Storage and overwintering. Overwintering is not an immediate problem to be dealt with for most microbial pathogens of arthropods. Relatively few invertebrate pathogens have any pronounced tendency to form overwintering or other resistant structures as an obligatory step in their routine propagation. Most cultures of microbes can be maintained in a vegetative state for an indefinite period, and nearly all microbes can be stored for prolonged times in a viable state by one of a large number of possible technologies. The most reliable storage technique usually involves physiological inactivation by lyophil (i.e., freeze-dried) or cryogenic storage.

Release from quarantine considerations

Decision to release from quarantine, including safety and environmental considerations It is incumbent on all investigators using microbial pathogens of arthropods to comply with APHIS requirements to file an EA with any request for any release of a microbe from containment into the open environment. Such documentation serves to focus the applicant's attention on important issues of environmental safety, particularly on nontarget effects at the proposed release site. An EA also serves an indirect beneficial purpose of providing an ongoing education to regulators about the organisms involved; this, in turn, provides a strong basis for speedier and well-supported regulatory responses to subsequent applications involving the same or similar microbials.

There is much concern among invertebrate pathologists about possible misinterpretations by regulatory officials of information on the host ranges of microbial pathogens. The major concern is that the ecological host range (that which is actually observed in unconstrained field conditions) is often much narrower than that which can be observed during experimental challenges of diverse hosts not otherwise known to be natural hosts of the microbe.

Very low rates of infections of honeybees or other beneficial insects may be observed during experimental host-range testing even though these insects may never be infected by the same microbe under natural conditions. Applicants are duty-bound to report any such induced mortality of bees or beneficial insects of which they are aware; the greatest fear is that such results may be misinterpreted by regulatory officials, be regarded as a sign of an unacceptable risk, and become the basis for an inappropriate decision to reject an application for environmental release.

Provisions for meeting FIFRA, NEPA and other federal and state regulations Most potential releases of exotic microbial pathogens of arthropods are intended for inoculative releases (i.e., classical biocontrol). As such, those releases will be made on areas which may never accumulate to the total 10 acre trigger point that will bring the release into a necessity to comply with EPA regulations under FIFRA covering pesticide releases; such an event would require the preparation of a full-blown EIS, completion of Tier I safety testing, and the granting of an EUP. APHIS decisions to allow or to bar any release from containment on areas under 10 acres will automatically lead to the satisfaction of NEPA requirements.

Any problem in fully complying with any pertinent state regulations is almost uniformly a problem of ignorance of those regulations; it is currently difficult to know whether many states have their own regulatory permitting process that might affect the process other than that routinely encountered during submission of requests for regulatory decisions sent through the states to APHIS. There is no question that investigators should strive to ascertain the existence and specific requirements of state regulatory authorities in any states where releases from containment are planned.

Field release by quarantine facility There was complete agreement among the discussants that all anticipated releases of exotic microbial pathogens of arthropods from containment should continue to be evaluated by APHIS. The appropriate vehicle for providing the necessary information to support APHIS in making its decision to approve or disapprove applications for microbial releases is the EA. The group did not spend time specifically discussing the differences between the

Short and Long Formats or the sets of criteria used to determine which format might be more appropriately used to prepare the EA.

Interstate shipment and export by quarantine facility

There should be no significant regulatory impediment to the interstate movement--particularly for organisms being moved between laboratories with appropriate facilities to maintain microbiological security and containment--or export of most insect microbials so long as necessary packaging requirements are observed. Most of these organisms can be shipped in pure cultures or in some other form completely free of any arthropod host material. Lists of states which have separate requirements for their own permits to be attached to shipments must be assembled and publicized; despite the very best of intentions to comply with such regulations, the awareness of such requirements (and which states have them) remains unacceptably low within the community of scientists working on arthropod pathogens. Most shippers must rely on the recipient's providing accurate information about the need for such shipments and obtaining any needed permissions and permits from the regulatory authorities of the receiving state.

There is even spottier knowledge regarding regulatory constraints governing exportations of microbial pathogens of arthropods. Again the burden is thrown on the recipients to ascertain what regulations may exist and to obtain any necessary permissions.

ARS facilities making shipments must submit an AD-944 form to the BCDC to establish an appropriate record of export. Facilities granted blanket permits for importation of microbial pathogens should also be required to provide periodic reports to APHIS and to the BCDC of all interstate shipments. Such reports should include full information of the nature of the material shipped together with the name and address of the recipient.

Documentation considerations

Record keeping Efforts should be made to computerize records of collections, accessions, cultures, vouchers and other specimens, and as many other pertinent aspects of the biology of microbial pathogens of arthropods as can be reasonably done. Microcomputer databases such as DBase-4 (for IBM and compatible equipment) and Fourth Dimension (for Macintosh) are proving to be adequate for

the development of such record keeping systems. There was broad support for full and regular submission of information requested by the ARS BCDC. It was additionally suggested that all U.S. facilities dealing with basic microbial pathogens of arthropods should list themselves with the database being sponsored by the CSRS Experiment Station Committee on Policy to list culture collections and microbial resources in the U.S. Information about this database and submission forms can be obtained from Dr. Larry Moore, Department of Plant Pathology, Oregon State University, Corvallis, Oregon.

Vouchers The nature of voucher materials to be deposited depends on the type of organism involved. Vouchers of bacteria and viruses should be live germplasm; microsporidia can be deposited (in cryogenic facilities, for example) as viable spores, as infected cadavers, or as microscope slides bearing smears and squashes of infected host tissues stained with Giemsa and hematoxylin. Fungal vouchers should be appropriate permanent specimens such as slides, dried sporulating cultures, or cadavers of infected hosts.

There was concern about the designation of appropriate sites for the deposition of voucher specimens. There was no general agreement about what facilities should be listed in Attachment 15 to the proposed Guidelines for specific microbial groups. Among all groups of arthropod pathogens, the most comprehensive repository is that for the fungi (i.e., the ARS Plant Protection Research Unit; Ithaca, New York). The Dulmage collection of *Bacillus thuringiensis* is deposited at the ARS Northern Regional Research Center (Peoria, Illinois), although a much larger collection of bacteria is maintained at the ARS Insect Biocontrol Laboratory in Beltsville, Maryland, even though the latter facility is not able to support requests for distributions of cultures. There are no truly adequate facilities established for depositions of microsporidia or viruses.

Group 5. Pathogens of Weeds *W. L. Bruckart, Chair*

The draft ARS Guidelines for microbial pathogens of weeds were discussed during the session, and a revision of the early draft was submitted later and appears, with additional emendations, in Appendix 3, E.

It was noted during the session that interagency review of proposals for planned research and for release of exotic weed pathogens is adequate through the TAG. However, there are no individuals with expertise in plant pathology on the TAG, and review by TAG of proposals for release of weed pathogens may be inadequate. It was recommended that APHIS provide specific in-house expertise for review of proposals to release weed pathogens. Also, APHIS should have the capability to set up science advisory panels for cases that require more detailed considerations.

Group 6. Natural Enemies and Antagonists of Plant Pathogens and Nematodes *G. C. Papavizas, Chair*

The draft ARS Guidelines for this group of organisms were discussed during the session, and the resulting revision, with additional emendations, appears in Appendix 3, F. The following additional suggestions were developed during the session.

- (1) PPO Form 526 is adequate for importation of potential MPCAs. It is suggested that the petitioner remark on the form that the organism to be imported is for biological control and indicate the pathogens he/she intends to control.
- (2) There is no need at this time to suggest creation of a Biological Control Advisory Group.
- (3) Since the end products from imported soils, cadavers and plant materials will be pure cultures in test tubes to be released to the petitioner (i.e., a non-containment laboratory) before release to the field and since only one strain in hundreds may be promising to be released to the field for small-scale experimentation, Group 6 believes that there is no need for a protocol and an EA for the release of cultures to the non-containment laboratory, provided such laboratory will use the culture for laboratory and growth chamber tests and will not distribute it to other laboratories. Only the final step, release to the field for small-scale experiments, should require an EA.

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Appendix 2. Screening Classical Weed Biocontrol Projects and Agents

**A Workshop Paper Contributed by
Peter Harris, Agriculture Canada Research
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Abstract (See page 24.)

Introduction

Biocontrol is the study and utilization of parasites, predators and pathogens to regulate populations of pests (Harley 1985). Classical weed biocontrol involves establishing these agents in a new region to give control on a continuing basis. The agents do not respect property boundaries and the prospects of getting a return on developmental costs through market sales are small as the agent finds the weed itself. Thus, classical biocontrol is largely done by government or with government funding in the public interest. Government is also responsible for protecting public interests to ensure that desirable plants and the ecology are not harmed. This is done by a review before agent release, which is the only stage amenable to regulatory control. Plant Protection Acts are designed to prevent the introductions of plant pests and by special dispensation they can be used to permit the introduction of weed biocontrol agents. However, the U.S. legislation does not distinguish between beneficial and noxious plants (Ramsay 1973) and the *Canada Plant Protection Act (1990)* classifies organisms that attack noxious plants as pests. The Acts and the mind set of the regulators is to regard all plant feeding organisms as bad, as was confessed by Ramsay (1973). It would be preferable to address biocontrol in a positive manner to approve agent release if it is likely to be of more benefit than harm, as stipulated in the *Commonwealth of Australia Biological Control Act (1984)*. In contrast to classical biocontrol, inundative biocontrol can be regulated at the market place on a continuing basis in the same manner as a chemical pesticide. In most countries, inundative biocontrol is under pesticide registration legislation. The public interests are somewhat different and these are not discussed here.

The purpose of the screening process in classical weed biocontrol is to avoid doing harm and this is as much concern to the researchers as the regulators; however, the present tests are largely done to satisfy the reviewers and

they cannot be changed unless the reviewers are receptive to other approaches. The process is expensive, slow and tends to inhibit innovation as do most regulations. The purpose of this talk is to identify the public interests that need to be protected and to discuss how this is best done.

I suggest that regulation needs to cover three areas: (1) that the project really is in the public interest, (2) that the candidate agent has a predictable host range, and (3) that agent establishment will be more beneficial than harmful. In the U.S., these broadly fall under the present mandate of the Technical Advisory Group (TAG) of USDA-APHIS PPQ. Issues that do not involve protection of the public should not come under regulatory control to avoid the same group being responsible for the promotion and the protection aspects of biocontrol.

Determination of Public Interest

Biocontrol is only in the public interest if there is a net economic return, but this can be from the environment as a whole rather than from the control of a specific weed. Ecologically the goals are regional such as to change the composition of the flora or displace the use of an environmentally detrimental herbicide. Because they are regional they must satisfy the public as a whole rather than a particular interest group. Thus, classical biocontrol is desirable if favored by the public and undesirable if there is sizeable public opposition. Even if the antagonism to the biocontrol of a particular plant is the result of misunderstanding, this should be rectified before biocontrol is started. Misunderstanding seems to be the reason for the opposition by dove hunters to the biocontrol of *Tamarix* in Texas (C. J. Deloach 1990, pers. comm.) which in other respects appears to be an excellent target.

Klingman and Coulson (1982) indicated the proposal to target a weed for classical biocontrol should be accompanied by a report covering: the need and benefits of using biocontrol against the weed, the taxonomy, distribution, life history of the weed, the importance of related economic and native plants, as well as any benefits of the target weed itself. These form the first four sections of Environmental Assessment Review required by APHIS and NEPA. However, I find it counterproductive to require this information with the agent screening data. It should be a separate report needed to obtain approval for

any biocontrol project. It costs about two scientist years (about \$400,000) to screen a single agent and several will probably be required for control of a weed. To spend this sort of money before it is known whether the biocontrol of the target weed will be supported is irresponsible. Furthermore, projects started as the result of public and political pressure, but not substantiated by economic data, tend to lose government funding before completion. This is wasteful even if the project is restarted later. For example, USDA studies on the biocontrol of toadflax were apparently terminated for lack of economic justification. We now have economic data for Canada, and the study has been reactivated with Canadian-Montana funding to the International Institute of Biological Control (IIBC). Unfortunately, little use could be made of the USDA screening tests on the moths in the genus *Eteobalea* since these were done with a complex of species without voucher specimens being kept of those used in the tests. It has cost as much as a project started from scratch. Similarly, the Canadian project for the biocontrol of hound's-tongue has inadequate data on losses with the result that there are now questions whether it should be the second priority for biocontrol in British Columbia. Continuity problems would disappear if projects were not started without adequate economic data.

One reason for TAG was to ensure that proposed weed biocontrol projects are in the public interest as a whole; they have to consider both conflicting interests and the ecology as a whole. It is not an enviable task, but their wide experience and affiliations makes them well suited for the job. My concern is that it is increasingly unacceptable to have ecological policy issues being determined solely by civil servants. The public can understand the issues and wants to have a say in what is done. For example, the introduced spotted knapweed tends to dominate the herbaceous community in Montana. It presently infests 26 million acres in the state and threatens 37 million acres or 40% of the state (Chicoine et al. 1988). It is displacing native flora and reducing the grazing for cattle, food for native fauna and the most effective herbicide, picloram, kills a broad spectrum of plants and contaminates ground water when used on coarse soils. On the other hand, knapweed is pretty, it is a good honey producer, the seeds are consumed by some wildlife and the rosettes are grazed in the spring by deer, sheep and cattle. I am sure that biocontrol can reduce the weed from a 100% to a 5% cover without damage to economic

crops or native plants, and it is the most economic means of solving the regional knapweed problem. I have no doubt that the public would reach the same decision as TAG, that the weed should be targeted for biocontrol.

I suggest that opening the review to the public achieves several things. (1) It puts the decision to target a weed for biocontrol on a sounder financial, moral and probably legal basis since public concerns are considered and, politically, funding tends to go to projects that have wide public support. (2) The program can be modified to take into account special concerns of which TAG was not aware. (3) There is an opportunity to educate the public about misunderstandings. (4) Both the proposer and TAG are likely to do a more thorough job if the proposal is to be published. (5) Presently, approval to target a weed for biocontrol is not always being obtained prior to screening an agent and this sometimes results in a considerable waste of time and money. (6) The proposed procedures might take less time than required at present because public scrutiny would keep TAG to a schedule. (7) The information on the weed would not have to be repeated every time approval is sought for the release of an agent, as is required at present under the APHIS and NEPA Environmental Assessment guidelines.

I suggest that proposals for the biocontrol of a weed should be submitted to TAG. TAG can turn them down, ask the proposer for modifications and additional information, or approve the project in principle. Projects approved in principle, should be published and public comments invited within a time limit. After an opportunity for rebuttal by the proposer, TAG would rule in favor of the biocontrol project, against it, hold further public hearings or, if the issue is too contentious, transfer it for a political decision. Rulings in favor should be accompanied by a list of special concerns (e.g., that the survival of certain native plants should not be compromised). This is roughly the procedure under the *Commonwealth of Australia Biological Control Act 1984*. The only difference to present procedure is that proposals for classical weed biocontrol should be published routinely and public comment considered. Precedent has been set as the U.S. Fish and Wildlife Service published the proposal to target purple loosestrife (*Lythrum salicaria* L.) for biocontrol (Thompson et al. 1987). A few public comments were received in Canada which were forwarded to TAG; but the

important point is that in Canada, I sense that the initial opposition to the project has changed to general support.

I would restrict TAG to review of proposals to target weeds for classical biocontrol and have the review of proposed agents done by another body. TAG members are not selected for their expertise in insect ecology and behavior, nor is work on this committee their main duty. Thus, the work load to cover both proposals on weeds and on agents is so great that decisions take a year or more. In interest charges alone, the delay of a year represents \$40,000 an agent. Apart from the cost, delay increases the risks since the public may take matters in their own hands as was done in Australia with the blackberry rust, *Phragmidium violaceum* (Schulze) Winter (Bruzzese and Field 1985), and may have happened in Canada with the diffuse knapweed rust, *Puccinia jaceae* Oth. var. *diffusa*. It was approved for release by Canada, but was not released by the Regina Research Station since there were strong objections from some members. A rust strain that is genetically distinct from that screened at Regina appeared in 1988 at several sites around Oliver, British Columbia, and has since spread to the whole diffuse knapweed region in the province (Mortensen et al., in press). I suggest that if decisions to prohibit the release of particular agents are going to be respected by the public: (1) they must be made within a reasonable time, (2) they should speak with one voice instead of a multiplicity of dissenting decisions, and (3) they should publish the decision with reasons for it.

Armed with a favorable TAG decision and the list of concerns, the proposer should submit a protocol for screening agents to a new body that I have called Agent Review Group (ARG). This would not be published. In the past, a list of test plants was approved, but this is only appropriate for single agent species. Thus, either many lists had to be approved or the list had to include many pointless tests, as has happened for spurge agents. For example, there is no point in testing foliage-feeding spurge insects on the spurges that lack leaves. Also, insects with a life history that needs the roots of a perennial or biennial for development will not attack annuals, so there is no point in testing them. There is no point in testing rare species of plants if the agent will not accept the common species in the same taxon or cannot survive in the habitat of the rare plant. In other words, the testing protocol should be a game plan with flexibility and reasons for the strategies proposed. It should also set limits of what is

unacceptable for an agent. Thus, if it is unacceptable for a toadflax biocontrol agent to develop on snapdragon, the researcher can test snapdragon initially and study in detail only those that do not accept it. At present the researcher has to second guess what TAG will find acceptable with the result that considerable time and money is sometimes wasted in detailed tests on organisms such as *Chrysolina gypsophylla* Kuest.(Rizza and Pecora 1980). Setting limits is in the interest of the reviewers in order to reduce the number of screening reports that have to be reviewed and help keep their decisions consistent. It would also reduce costs without compromise of safety.

Determination of Agent Host Range Predictability

Laboratory host range determinations to show that all desirable plants are safe from attack are impossible and attempts to guess the basis of host selection by testing plants with similar morphological or chemical features has not been rewarding. The only laboratory method with predictive value has been “choice” and “no choice” tests starting with the known host and proceeding to increasingly distant taxa (Harris and Zwölfer 1968, Zwölfer and Harris 1971, Wapshere 1974). The “no choice” tests show the range of plants that will support normal agent development in the laboratory. These must form a pattern that can be used to predict its host range in the field, such as plants in a species group or genus, for it to be acceptable as a biocontrol agent. Organisms attacking diverse weeds such as Canada thistle and leafy spurge are unsuitable, since they do not allow prediction of what else might be attacked, as are those with predictable ranges that include desirable plants. Plants unsuitable for development in the laboratory are safe from attack in nature, but so are many plants that support development in the laboratory. For natural utilization, the plant must grow in a site that meets the ecological requirements of the agent and the agent must find and accept it for oviposition. Thus, the ability to develop on a plant in the laboratory measures one parameter that is necessary. Tests of insect discrimination for oviposition sites are generally inconclusive in the laboratory. The female becomes disoriented and tends to oviposit at random. The tests need to be done with natural populations in the field with pots of test plants. For example, the larvae of *Eteobalea intermediella* Riedl from Yugoslavian Dalmatian toadflax oviposited and developed on snapdragon in laboratory tests but did not oviposit on it in the field (Saner et al. 1991). This and the

fact that snapdragon is normally grown in moister habitats than those required by the moth are the reasons that it is not attacked in nature.

Stenophagous insects that can develop on several plant species, attack on the basis of plant abundance and its suitability for larval development (Rausher 1980, and review in Harris 1990). Thus, scattered rare plants and those poorly accepted in laboratory feeding tests are not attacked in nature. It might be possible to quantify the relation between laboratory feeding levels to field attack. This would have to be a cooperative study as I do not have enough Canadian data for statistical significance; but I suspect that plants supporting less than 75% of the feeding on the normal host are rarely attacked. Researchers lack enthusiasm for doing such studies as they perceive the reviewers to be unwilling to use any criteria except the survival or lack of it in laboratory feeding tests. Few reviewers attend the discussions at the International Symposia on Weed Biocontrol and the absence of any response to papers such as Mortensen (1985) that suggest changes, indicate that they have little time for background reading in weed biocontrol. The result is that the starvation test has become a tyranny that has displaced studies that I find more meaningful such as the survey of related plants in the country of origin as done by Zwölfer (1965) for the European thistles. The survey not only showed the range of plants attacked by the insects in the field, but also that some insect genera were restricted to a plant taxon. For example, the weevil genus *Larinus* is only found on plants in the subfamily Cynaroideae and genus *Bangasternus* is restricted to the subtribe Centaureinae.

The Cynaroideae is an old subfamily that was divided between continents with the break-up of Gondwanaland. Thus, the restriction of *Larinus* to it in Europe and Asia as well as to plants that have evolved independently in southern Africa (Clark 1988) indicates an extremely stable association. Instead of data of this type, the reviewers seem to want a system by which they can check whether the insect has passed or failed a specific test, since they insist on starvation tests being done on plants that cannot possibly be hosts. It is unreasonable to expect reviewers, who are primarily responsible for other duties, to attend international discussions on screening agents or to do extensive background reading in weed biocontrol. Thus, this difficulty is likely to remain, but it would help to select people with an extensive background in insect ecology and behavior.

There is another problem which would be solved by insisting on taxonomic verification of specimens that survive in the screening tests. For example, Gagné (1990) found that the leaf bud gall midge on cypress spurge in western Europe was *Spurgia capitigena* (Bremi) and that from leafy spurge in the San Rossore area of Italy was *S. esulae* Gagné. The screening tests of those from San Rossore leafy spurge showed that they developed on both cypress and leafy spurge (Pecora 1983). The assumption that all those in the test were *S. esulae* was apparently incorrect as both species are now established in North America from San Rossore leafy spurge. My studies indicate that *S. capitigena* develops on both spurges although it prefers cypress spurge while *S. esulae* does not attack cypress spurge. With hindsight, the problem would have been solved if the specimens developing on cypress spurge had been submitted to Gagné. In a sense both species were screened although it is not known which plants were exposed to the apparently low *S. capitigena* population. As cypress spurge is a weed in its own right and it is clear from the European literature that *S. capitigena* has a restricted host range, its establishment will be beneficial. However, for the sake of credibility we need to know before release that there are two species. [Editors' Note: There may be apparent inaccuracies in the comments in this discussion on the *Spurgia* insects; for clarification, interested readers should contact P. C. Quimby, ARS Rangeland Weeds Laboratory, Bozeman, Montana.]

The best indication of what is likely to happen in North America is the field situation in the native region. For example, insects confined to the genus *Carduus* throughout Europe are most unlikely to attack native *Cirsium* spp. in North America regardless of what they do in laboratory feeding tests. Insects restricted to attack *Euphorbia* in open dry coarse soils will not attack North American spurges that grow in swamps or in the shade. Similarly, if all strains of an insect are restricted to northern Europe, the species is no more likely to survive in southern North America than it does in southern Europe. There are computer mapping techniques to predict distribution from the climate at a series of known sites. I suggest that as soon as a program can be modified for North America, its use to predict the North American distribution should be required to obtain release approval.

In conclusion, I would like to see more emphasis on field surveys of plants related to the target weed in the country

of origin, distribution maps of the agent at its origin and the predicted distribution in North America as well as detailed descriptions of its site requirements and experimental releases of candidate agents in its country of origin in other habitats. Such studies should be given as much or more weight as feeding tests. The identity of insects surviving the screening tests should be verified by a taxonomist to ensure that the culture tested is not a mixture of two species.

Determination of Agent Desirability

An Environment Assessment on each candidate agent would be submitted to ARG to obtain approval for its release. The aspects that ARG need to consider range from the host plant and habitat requirements of the agent, the type of damage likely to be most harmful to the target weed (Harris, in press), to the interpretation of feeding tests and field data, and the effects of parasitism and competition. I will discuss parasitism and competition as they have caused difficulties.

Keddy (1989) defined competition as the negative effects which one consumer has on another by consuming or controlling access to a resource that is limited in availability. Clearly, if the agent remains so scarce that there is no competition, the weed will not be controlled. Thus, competition is essential in weed biocontrol. Hairston et al. (1960) postulated that while carnivores should compete inter-specifically, herbivores should not, because their populations are suppressed by natural enemies. This hypothesis was supported by Lawton and Strong (1981) who found that competition between folivorous insects is usually low. Thus, it appears to be a paradox that weed biocontrol is ever successful. It can be successful when the mortality from natural enemies is low enough that the agent increases until the resource becomes limiting. This requires the introduction of agents without their specialized natural enemies as well as the selection of species that will not be heavily attacked by enemies in the new region. Goeden and Louda (1976) showed that failures have occurred for both reasons. Thus, certain taxa, such as cecidomyiid gall formers, which are heavily parasitized in North America, should be given a low priority as biocontrol agents (Harris, in press).

Entomophagous parasites can be easily eliminated by laboratory rearing, but not microsporidian and virus

diseases. I suggest that public interest is best served by not releasing mass collected foreign stock when there are disease free and well adapted colonies established in North America. This is the situation with several *Aphthona* spp. flea beetles established on spurge, so we should not run the risk of introducing their microsporidian diseases. Also, without investigation, it is not certain that collections from other sites have the same host range as those approved for release. For example, Unruh and Goeden (1987) showed that *Rhinocyllus conicus* (Froelich) from *Carduus* and from *Silybum* are genetically distinct populations with different host ranges. Thus, release of the *Silybum* population should have been reviewed before being approved for release. Similarly, yellow toadflax in North America is attacked by the weevil, *Gymnaetron antirrhini* Payk., but not Dalmatian toadflax although it is a host in Europe. Electrophoresis of European *G. antirrhini* from Dalmatian toadflax showed that it is distinctly different from the population on yellow toadflax (R. M. Nowierski 1990, pers. comm.) so it should be tested and the results submitted to ARG for review before release in North America.

The absence of natural enemies will increase intra-specific competition, but if consumption is still insufficient to control the weed, it is necessary to establish other species of agents on it. The problem is that there are two basic types of competition (Keddy 1989). Interference competitors (organisms that directly suppress their neighbors) should be avoided, since as the weed becomes scarce, they act in the same way as natural enemies to reduce the level of exploitation, although sometimes the interference is too low to matter (Story et al., in press). In contrast, exploitation competition is indirect and involves the reduction of the resource. In simplistic terms, the species that eats most or eats it first, wins. Displacement of the less effective exploiters does not compromise the effectiveness of biocontrol, so the only risk is the cost of screening.

The capitula of diffuse knapweed, are attacked by a sequence of sympatric exploitative competitors and a few interference competitors (Harris 1989). The number probably depends on the richness of the resource in recent geological history (Southwood 1961). The models of Akcakaya and Ginzburg (1989) indicated that niche overlap between sympatric species tends to decrease with evolution as each species specializes on what it does best. In such cases, consumption of the host increases with the number of exploitative competitors, since each consumes

some of the resource missed by the former. This suggests that the more sympatric specialists common on a weed at its origin, the more agents will be required for control, and the more expensive the project.

In conclusion, public interest is not harmed by introducing several exploitative competitors, so this is not a concern of ARG, although if unnecessary species are introduced, it is a concern to funding agencies. The introduction of an interference competitor that reduces the amount of damage done to the weed by other agents does affect public interest and hence is a concern of ARG.

Summary

(1) Weeds should be approved as targets for biocontrol before agent screening is undertaken. The requirements that need to be covered are essentially those in the first four sections of the APHIS and NEPA Ecological Assessment outline.

(2) TAG should review the proposals for classical weed biocontrol; and those approved in principle should be published and public comments invited. Formal approval with a list of concerns would be made by TAG after review of the comments.

(3) A new body, ARG, should be established to approve protocols for screening agents and to set host range limits that are acceptable in species approved for release.

(4) ARG should review the agent screening reports (the second half of the APHIS and NEPA Ecological Assessment outline) and be responsible for recommending release approval to APHIS.

(5) Permits should not be given for release of agents from different host plants or different regions from those screened without tests to show that they are the same. Genetically distinct populations should be screened, and approved by ARG before release.

(6) Organisms completing development on test plants should be submitted for taxonomic verification.

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**Appendix 3. Proposed ARS
Guidelines for the Introduction and
Release of Exotic Organisms for
Biological Control Research and
Development in the United States**

Drafts of the following six Guidelines and Summary documents were prepared prior to the ARS Workshop. Although most of the procedures included in the Guidelines have long been followed by ARS biological control scientists, they have never been previously presented in comprehensive form. Until 1972, most of the ARS classical biological control program was administered by a central ARS office, under which these procedures were largely developed. These proposed Guidelines documents have been prepared because of ARS reorganizational events since then, the increased number of ARS scientists and facilities involved in classical biological control research, and the promulgation of a number of environmental laws and regulations that impact classical biological control programs in the United States. The Guidelines presented here have been revised from the original drafts as a result of the scientific reviews conducted during the Working Sessions at the ARS Workshop, and subsequently by other ARS and University biological control scientists.

These Guidelines are herewith proposed for adoption by ARS, and refer to some existing procedural problems and questions, and contain some special proposals and other recommended procedural matters designed to permit the continued safe conduct of classical biological control research while meeting the provisions of recent legislation and environmental concerns of the general public. Some of these specific proposals and recommended procedures, which are clearly indicated by [BRACKETING] and **boldfacing** in the Guidelines, require further consideration by ARS, APHIS, and/or EPA offices, and/or further review by scientific panel; all proposals and recommendations, and questions, requiring such reviews are listed in the final section of this Appendix.

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Proposed Summary Guidelines

Proposed ARS Guidelines for Importation, Interstate Movement, and Release of Exotic Organisms for Use in Biological Control [or Pollination] Research and Development Programs in the United States and Territories

The purpose of this document is to establish policy concerning ARS procedures for importing and releasing exotic organisms in the United States for **pollination studies** and for use in biological control of pests such as insects, nematodes, snails and other invertebrates, weeds, and plant pathogens.

I. General

Many organisms occurring in various parts of the world are of great potential benefit to U.S. agriculture for use in biological control of pests and **crop pollination**. The importation and evaluation of these exotic organisms are important research responsibilities of the Agricultural Research Service. However, exotic material intended for beneficial purposes must be imported and released in such a manner that will insure that every reasonable precaution is taken to contain and prevent the escape or release of organisms that are injurious to agricultural, horticultural, or forestry commodities, humans and domestic animals, or other beneficial invertebrates, or that are otherwise detrimental to the environment. It is also essential that appropriate liaison be maintained among all agencies engaged in activities involving the introduction and release of exotic organisms. The procedures described in this document and associated Guidelines have been prepared in accordance with the requirements of the Plant Quarantine Act of 1912 and Federal Plant Pest Act of 1957, prohibiting the importation and movement of plant and animal pests, pathogens, vectors, and articles that might harbor such organisms, unless authorized by the U.S. Department of Agriculture, and of the National Environmental Policy Act of 1969 (NEPA) and other Federal and State regulations impacting ARS biological control and **pollination** research and development programs.

The following general procedures are designed to assist in providing needed precautions and liaison. Individual copies of the detailed Guidelines specifically related to each of the several types of organisms to be imported are available from the National Program Staff (NPS), ARS, USDA, Beltsville, Maryland 20705, or the ARS Biological Control Documentation Center (BCDC). The organisms covered include arthropod parasites ("parasitoids"), predators, and competitors (such as dung beetles), nematodes, and microbial pathogens (viruses, rickettsia, protozoa, bacteria, and fungi) for control of arthropod pests; plant-feeding arthropods, plant nematodes, and microbial pathogens for control of weed pests; and other organisms for control of plant nematodes and plant pathogens. *Proposed* additional guidelines include those for: **microbial or invertebrate organisms for control of snails and other invertebrate pests other than arthropods and nematodes; vertebrates (e.g., birds, toads, and fish) and plants for control of insects, weeds and other pests; and insect pollinators.**

II. General Procedures

A. Importation and Movement Most living invertebrate organisms for use in **pollination** or biological control research studies shipped from foreign sources into the United States by or for ARS employees must be under permit and accompanied by appropriate permit labels issued under the auspices of the Animal and

Draft Guidelines (Summary, page 1)

Plant Health Inspection Service (APHIS), USDA. Permits for importation of vertebrates will be issued under the auspices of the U.S. Department of Interior. Shipment of most biological material is regulated by Federal statute, and by some State laws. Although some types of biological material may not be specifically regulated, the policy of ARS is to require shipment permit labels for all such material in order to guard against importation of potentially hazardous organisms. Exceptions to such requirements are stipulated in the more specific Guidelines, as are procedures for application for permits or shipment labels for importation and release of exotic organisms, which may require approvals from appropriate State officials. Permit application forms are available from BCDC or APHIS. APHIS and BCDC will maintain copies on file of all applications for importation or movement of beneficial organisms.

B. Facilities and Operational Procedures Most organisms for **pollination** or biological control studies shipped into the United States from foreign countries, with the exception of certain organisms originating in Canada or Mexico, will be processed through a Quarantine Facility or other proper facilities that have been inspected and approved by APHIS for receiving the kind of material being imported, in accordance with specific approved Guidelines. **Each ARS Quarantine Facility will operate under a Compliance Agreement or Memorandum of Agreement between APHIS, ARS, and pertinent State regulatory agency, and all ARS facilities approved for initial receipt of foreign shipments will operate under an approved set of Operational Procedures based on the Guidelines, and will have a duly appointed Quarantine Officer or other official who is responsible for insuring that proper procedures are followed. Operational Procedures will be approved and Quarantine Officers will be appointed by the appropriate ARS official after consultation with NPS and the appropriate Laboratory Chief or Research Leader, and APHIS office. Specifications for facilities and guidelines for their operation are included in the specific Guidelines for each type of organism imported attached hereto, individual copies of which are available from NPS or the BCDC. APHIS, State, and/or ARS officials will periodically inspect these facilities to insure their adequacy and that these procedures are being followed.**

C. Field Release A permit is generally required for the initial release of a foreign organism into the field in the United States, and in many cases an Environmental Assessment (EA) is also required in order to meet the requirements of NEPA. The issuance of permits and development of EAs for release of invertebrate and microbial biological control agents and insect pollinators is the responsibility of APHIS. ARS scientists are responsible for providing the necessary data to APHIS for EA development and permit issuance, or for development of the EA themselves. ARS scientists are also responsible for adherence to the requirements of the Federal Insecticide, Fungicide and Rodenticide Act of 1947 (FIFRA) as amended in the further development of exotic microbial biological control agents, including obtaining Experimental Use Permits (EUPs) for field studies involving 10 acres or more (or more than one acre of water), and following other procedures under Environmental Protection Agency (EPA) regulations for development of microbial pesticide products. ARS scientists are also responsible for knowledge of and adherence to the pertinent laws and regulations of the State(s) in which importations or releases of foreign biological control organisms are to be made.

D. Documentation of Importations, Shipments, and Releases A permanent record will be made of all importations, quarantine consignments, many shipments, and all releases of exotic organisms for **pollination** or biological control studies in which ARS personnel are involved. AD Forms 941, 942, and 943 (for invertebrates), and 944 and 944A (for microbials), which are designed to provide source data for the material shipped or released, and feedback information on the receipt of shipped material, or similarly detailed documentation procedures, will be used for documenting importations, quarantine consignments, shipments, and releases. A copy of all documentary forms will be sent to BCDC. In many cases, voucher specimens

Draft Guidelines (Summary, page 2)

documenting the field release of the organism also will be required. The Quarantine Officer or other responsible scientist is specifically assigned the responsibility for assuring that proper records are maintained and that voucher specimens are prepared. Further specific information on documentation forms and procedures and voucher specimens is included in each of the individual Guidelines.

III. Available Guidelines

1. Guidelines for the Importation, Interstate Movement, and Field Release of Foreign Arthropod Biological Control Agents (Parasites ["Parasitoids"], Predators, and Competitors) into the United States for Arthropod Pests of Plants, Humans, and Domestic Animals, and Vectors of Plant, Human, and Animal Pathogens, and for the Interstate Movement and Export of Such Beneficial Arthropods
2. Guidelines for the Importation, Interstate Movement, and Field Release of Foreign Arthropod-Parasitic Nematodes into the United States for Biological Control of Arthropod Pests of Plants, Humans, and Domestic Animals, and Vectors of Plant, Human, and Animal Pathogens, and for the Interstate Movement and Export of Foreign and Native Arthropod-Parasitic Nematodes for Research on Biological Control of Such Pests
3. Guidelines for the Importation, Interstate Movement, and Field Release of Foreign Arthropods and Nematodes into the United States for Biological Control of Weeds, and for the Interstate Movement and Export of Foreign and Native Arthropod and Nematode Natural Enemies of Weeds
4. Guidelines for the Importation, Interstate Movement, and Field Release of Foreign Microbial Pathogens (Fungi, Bacteria, Rickettsia, Viruses, Protozoa) into the United States for Biological Control of Arthropod Pests of Plants, Humans, and Domestic Animals, and Vectors of Plant, Human, and Animal Pathogens, and for the Export of Foreign and Native Arthropod Pathogens for Research
5. Guidelines for the Importation, Interstate Movement, and Field Release in the United States of Foreign Microbial Pathogens for Biological Control of Weeds, and for the Interstate Movement and Export of Foreign and Native Pathogens of Weeds for Research
6. Guidelines for the Importation, Interstate Movement, and Field Release of Foreign Beneficial Organisms (Microbial Pathogens and Antagonists) into the United States for Biological Control of Plant Nematodes and Plant Pathogens, and for the Export of Such Organisms (Foreign and Native) for Research

Some additional needed Guidelines:

- (1) Introduced invertebrates and other organisms for biological control of snails;
- (2) Introduced snails and other invertebrates (other than arthropods and nematodes) for biological control purposes;
- (3) Introduced plants for biological control;
- (4) Introduced pollinators; and
- (5) Introduced vertebrates for biological control.

**Proposed ARS Guidelines for
the Importation, Interstate Movement, and Field Release in the United States
of Foreign Arthropod Biological Control Agents
(Parasites/Parasitoids, Predators, and Competitors)
for Arthropod Pests of Plants, Humans, and Domestic Animals,
and Vectors of Plant, Human, and Animal Pathogens,
and for the Interstate Movement and Export of Foreign and Native Species
of Such Beneficial Arthropods**

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Attachments

1. PPQ Form 526: Application and Permit to Move Live Plant Pests or Noxious Weeds
2. Proposed PPQ/ARS Form __: Application and Permit to Move Living Beneficial Organisms
3. List of ARS Biological Control Quarantine Facilities Approved for Receipt of Foreign Arthropod Parasites and Predators of Arthropod Plant Pests and for Foreign Biological Control Agents for Arthropod Medical and Veterinary Pests
4. List of Plant Regulatory Officials of U.S. States and Territories, Canada, and Mexico
5. VS Form 16-3: Application for Permit to Import or Transport Organisms or Vectors
6. AD Form 941: Biological Shipment Record - Foreign/Overseas Source
7. Form ARS-748: Identification Request
8. Proposed Structure and Procedures of the Proposed Biological Control Advisory Committee (BCAC)
9. Proposed List of Invertebrate Biological Control Agents Exempted from the Requirement of a Formal Environmental Assessment
10. Proposed Criteria for Exemption of Invertebrate Biological Control Agents for Arthropods from the Requirement of a Formal Environmental Assessment for Field Release
11. Proposed Abbreviated Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Exotic Invertebrate Biological Control Agents of Arthropod Pests: Short Format
12. Proposed Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Biological Control Agents: Long Format
13. Proposed Criteria for Biological Control Agents Requiring Either (1) an Abbreviated or (2) a Detailed Protocol Document for Providing Environmental Assessment Information
14. Proposed List of Arthropod Parasites and Predators Exempted from the Requirement of a Tolerance for Residues in Stored Food Products in Warehouse or Related Situations

Attachments (Continued)

15. List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries
16. AD Form 942: Biological Shipment Record - Quarantine Facility
17. AD Form 943: Biological Shipment Record - Non-Quarantine
18. **Proposed** Structure and Procedures of the U.S. National Voucher Collection for Introduced Beneficial Arthropods

¹ Original draft prepared in 1978 by J. R. Coulson, R. J. Dysart and R. R. Blume (ARS) and T. W. Fisher (University of California); revisions by R. W. Fuester and J. R. Coulson, with comments provided by L. R. Ertle and G. T. Fincher (ARS), H. W. Browning (University of Florida), and K. V. Teramoto (Hawaii Department of Agriculture) during 1990, and following review by Working Session participants (see Appendix 1) in January, 1991; further comments incorporated from later reviews by T. W. Fisher, G. Gordh, and E. F. Legner (University of California).

I. Intent and Scope of these Guidelines.

Since the 1880s, many insect pests introduced from one continent to another have been successfully managed by means of importing the pests' natural enemies from the country of origin. This approach is called classical biological control. Quarantine handling of natural enemies is a vital link between the foreign exploration and the colonization phases of the operation. These Guidelines are intended to outline the detailed procedures required for the continued safe importation, interstate shipment, and field release of foreign arthropod biological control agents (parasites/parasitoids, predators, and competitors) for arthropod pests of plants, humans, and domestic animals, and vectors of plant, human, and animal pathogens, for biological control research and development programs in the United States. These procedures are designed to insure that every reasonable precaution will be taken to contain and prevent the escape or accidental release of new plant, animal, or microbial organisms injurious to agricultural, horticultural, or forestry commodities, humans and domestic animals, or to other beneficial arthropods (e.g., hyperparasites), or that are otherwise detrimental to the environment.

Organisms for which these Guidelines are intended are limited to species of the Phylum Arthropoda, particularly of the Classes Insecta and Arachnida that are: 1) to be studied or utilized as parasites/parasitoids or predators in the suppression of arthropod pests of plants and vectors of plant pathogens; and 2) to be studied or utilized as parasites/parasitoids, predators, or competitors (e.g., dung beetles) in the suppression of arthropod pests associated with dung, or that are otherwise pests of humans and domestic animals or vectors of human and animal pathogens. For plant pests, these include primarily, but are not limited to, natural enemies in the insect Orders Neuroptera, Heteroptera, Coleoptera, Diptera, and Hymenoptera, and in the arachnid subclass Acari. For medical and veterinary pests, these include particularly species of the insect Order Coleoptera, Families Histeridae, Staphylinidae, and Scarabaeidae (subfamilies Scarabaeinae, Aphodiinae, and Geotrupinae) for use in the biological suppression of dung-breeding Diptera, and species of parasites and predators similarly associated with animal dung or with arthropod pests or vectors of human or animal pathogens, such as certain species of the insect Order Hymenoptera and of the arachnid Subclass Acari. Separate Guidelines exist, or are in preparation, for the importation of arthropods for control of pests in other animal and plant taxa, for the importation of members of other animal phyla and of pathogens for the control of arthropod pests, and for pollinating arthropods.

Statement on Risks Associated with Release of Arthropod Parasites and Predators.--Releases of exotic arthropod parasites and predators of arthropod pests seldom represent a significant threat to endangered species or other nontarget organisms because (1) emphasis is generally placed on rather host specific natural enemies to begin with, (2) generalist parasites and predators usually have poor searching abilities and tend to feed preferentially on whatever is abundant, and (3) density-dependent processes nearly always preclude significant attack rates at low host/prey densities (such as those likely to occur in the case of an endangered species). Since its introduction after the turn of the century, the super polyphagous parasite *Compsilura concinnata* (Meigen) (Diptera: Tachinidae) has been recorded from over 200 hosts (Sabrosky & Reardon 1976), but there is no indication that it has had a profound impact on any native species. Probably the most important cause of animal extinction is habitat destruction. It seems more likely that extinction or endangerment of a nontarget species would occur because of interspecific competition with an exotic invader or pesticide treatments used to suppress it, than by a natural enemy that needs it as host or prey in order to survive.

Legner (1986) and Coulson and Soper (1989) reviewed the risks associated with biological control studies from which can be derived the following conclusions: (1) Arthropod parasites and predators of insects and other arthropods present the lowest environmental risk of all categories of biological control agents; and (2) As a consequence of biological control programs, over 600 insect parasites and predators have been imported into the continental United States, of which more than 200 have become established. Of these, only two species (both hymenopterous secondary parasites introduced in the early 1900s when biological control was in its infancy) are believed to have had detrimental effects, and these are of little importance. Current protocols would not allow for the introduction of such species.

It is felt that the procedures proposed in these Guidelines reflect a conservative interpretation of these findings and that little environmental risk will result from their implementation.

These Guidelines also include procedures for the interstate movement and export of native or naturalized biological control agents for biological control of arthropod plant and medical and veterinary pests.

Some organizational abbreviations used in these Guidelines are:

APHIS - Animal and Plant Health Inspection Service, USDA
ARS - Agricultural Research Service, USDA
BCAC - Interagency Biological Control Advisory Committee **Proposed**
BCDC - Biological Control Documentation Center, ARS
EPA - Environmental Protection Agency
FDA - Food and Drug Administration
FWS - Fish and Wildlife Service, USDI
PHS - Public Health Service, USDHHS
PPQ - Plant Protection and Quarantine, APHIS
SEL - Systematic Entomology Laboratory, ARS
USDA - United States Department of Agriculture
USDHHS - United States Department of Health and Human Services
USDI - United States Department of Interior
VS - Veterinary Services, APHIS

II. Summary of Procedural Policies and General Safety Considerations.

A. Summary of Procedures for Importation, Interstate Shipment, Field Release, and Export of Arthropod Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests.

The Plant Quarantine Act of 1912 and the Federal Plant Pest Act of 1957 prohibit the importation and movement of plant and animal pests, pathogens, vectors, and articles that might harbor these organisms, unless authorized by the U.S. Department of Agriculture (USDA). The National Environmental Policy Act of 1969 (NEPA) contains provisions that impact upon the release of exotic organisms into the environment. Regulations under these Acts are enforced by the Plant Protection and Quarantine Programs (PPQ) and Veterinary Services (VS) of the Animal and Plant Health Inspection Service of the USDA. The importation and shipment of pathogens and vectors of pathogens of humans are regulated by the Public Health Service (PHS), USDHHS; if such importations or movements are contemplated by ARS facilities, information on these regulations can be obtained from the Foreign Quarantine Program, Centers for Disease Control, PHS, USDHHS, Atlanta, GA 30333, or PHS Quarantine Stations at U.S. ports of entry.

The determination of the adequacy of quarantine (or containment) facilities for receipt and laboratory testing of foreign organisms, and of the technical competence of investigators, is the responsibility of APHIS (PPQ and VS), and pertinent State Departments of Agriculture, and PHS in the case of importation of vectors of human pathogens. Determining the requirements that must be met for introduction of such organisms into quarantine or into the field is also their responsibility. APHIS and PHS want to assure that safety considerations such as those listed below are made prior to importation or field release of foreign biological control organisms in the United States. [NOTE: THE FOLLOWING STATEMENT CONTAINS A PROPOSAL AND IS RETAINED PENDING ACTION BY ARS, APHIS, AND OTHER AGENCIES.] In the case of foreign beneficial organisms for biological control, an interagency Biological Control Advisory Committee (BCAC) has been (proposed to be) established to provide technical support and advice to APHIS (and the PHS as may be required) and researchers, upon request, on proposed importations and releases of foreign biological control agents in the United States. [CLOSE OF STATEMENT]

Certain of the below listed safety considerations can be made during the overseas exploration phases of a biological control introduction program, i.e., before importation of the proposed biological control agent, while others can be made during the domestic quarantine phase of the introduction program. The procedures detailed in these Guidelines are designed to assure that such considerations are made and necessary precautions are taken.

It is highly recommended that the following references be studied in conjunction with these Guidelines: Fisher (1964); Lima (1983); Fincher (1986); Legner (1986); Coulson and Soper (1989); Ehler (1990); Way (1990); Howarth (1991); Roth et al. (1991); and Fisher and Andres (in press).

The more important conditions required for the importation and release of foreign beneficial arthropods for control of arthropod pests as reflected in these Guidelines, can be summarized as follows:

- 1) All foreign organisms shipped to the United States or later shipped interstate must be shipped in containers meeting USDA standards, and must be shipped with APHIS (and as necessary PHS) approval. See Sections III.A-B, and V.C.
- 2) Foreign arthropods for biological control, with few exceptions, must be received in quarantine (containment) facilities approved by APHIS (and PHS as necessary), where all necessary testing prior to release must be conducted under strict quarantine conditions, and where all material deemed to be of potential hazard or detriment is to be destroyed. A trained Quarantine Officer will be duly appointed who will be responsible for all quarantine operations. See Sections IV.A-C.
- 3) Authoritative identifications of the foreign organisms are required prior to their release or consignment from quarantine, and for the most part all safety considerations as listed below must be made prior to such release/consignment. See Section V.A.
- 4) Voucher specimens to document the field release of exotic organisms are required, and certain other documentary procedures are to be followed, during which APHIS and other officials are to be kept informed of all releases and shipments. See Sections III.C, IV.D, and V.D-E.
- 5) For interstate shipment and export of beneficial arthropods, adherence to quarantine requirements of the pertinent States and Territories of the United States and foreign countries is necessary prior to the shipment of the beneficial arthropods into those States, Territories, or countries. See Sections V.C.3, VI, and VII.

B. Safety Considerations Required for Importation and Field Release of Foreign Arthropod Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests in the United States.

The following safety considerations, discussed further throughout these Guidelines, must be evaluated prior to considering the importation or release of foreign beneficial arthropods into the United States:

1. For Parasites and Predators of Arthropod Plant Pests.

a. Protection against entry of plant pathogens or weeds.

Entry of host plant material must be restricted as much as possible; if entry of plant material is required, it must be destroyed in quarantine. Potential arthropod vectors of plant pathogens need study to assure elimination of foreign pathogens.

b. Protection against entry of arthropod plant pests.

Entry of exotic arthropod host/prey material must be restricted as much as possible; if entry of such organisms is required, they must be destroyed in quarantine. Knowledge is required that the biological control agent itself is not a plant-feeder or otherwise a potential plant pest; if one stage is a plant-feeder (e.g., some predators), the extent of potential damage and potential plant host range should be determined, as well as any potential for vectoring plant diseases.

- c. Protection against entry of arthropods hazardous or nuisances to humans or domestic animals.

Knowledge is required that the biological control agent will not harm vertebrates or will not contribute to the adulteration of human foodstuffs.

- d. Protection against entry of arthropods and other organisms inimical to native or other introduced beneficial arthropods.

Provisions are required for the elimination of all obligatory hyperparasites; facultative hyperparasites should also be eliminated except under circumstances where potential benefits can be shown to outweigh potential detriments. Likewise, the potential effect of the biological control agent on non-target organisms, e.g., biological control agents for weeds, predators, pollinators, endangered species, etc., should be considered; if a parasite attacks hosts in taxonomic groups which include primarily beneficial species (e.g., the Coccinellidae), host specificity studies are required to determine the safety of beneficial species. In addition, precautions should be taken that any entomopathogens capable of severely affecting beneficial arthropods are eliminated prior to release of imported arthropods in the United States.

The degree of risk involved as to potential detrimental effects of a natural enemy of a pest that may also attack non-target organisms (as in b, c, and d above) should be weighed against the potential beneficial effects of the natural enemy proposed for release. Emphasis should be placed on obtaining information needed in these cases from field studies in the country of origin, as much as possible, rather than on laboratory tests which may be misleading.

2. For Parasites, Predators, and Competitors of Arthropod Medical and Veterinary Pests.

- a. Protection against entry of livestock or human pathogens or parasites.

The entry of dung, the diet of both adult and immature stages of dung-breeding scarab beetles and the habitat of many predaceous or parasitic histerid and staphylinid beetles, hymenopterous wasps, and mites, is restricted; manure, or dung, cannot be imported unless it is of U.S. origin, and must be destroyed in quarantine as soon as possible. The entry of foreign arthropod hosts/prey that are pests of humans or livestock or known or potential vectors of human or animal pathogens must be restricted as much as possible; if entry of such pest arthropods or vectors are absolutely required, they must be received under special permits in specially approved quarantine facilities and destroyed in quarantine as soon as possible. Beneficial arthropods proposed for introduction that are potential vectors of livestock and human diseases need thorough study to assure elimination of foreign pathogens and parasites.

b. Protection against entry of arthropod plant pests.

Knowledge is required that the biological control agent itself is not a potential plant pest; if one stage is a plant-feeder (e.g., some species of Aphodiinae), the extent of potential damage and potential plant host range should be determined, as well as any potential for vectoring plant disease prior to importation; every effort should be made to find alternative non-plantfeeding biological control agents in such cases.

c. Protection against entry of arthropods hazardous or nuisances to man or domestic animals.

Knowledge is required that the biological control agent will not significantly aggravate already existing problems associated with internal parasitism in livestock and poultry, to include knowledge of the potential for vectoring human or animal diseases, and that the agent will not otherwise harm humans or livestock.

d. Protection against entry of arthropods and other organisms inimical to native or other introduced beneficial arthropods.

The potential effect of the biological control agent on non-target organisms, e.g., predators, parasites, beneficial dung-breeding organisms, endangered species, etc., should be considered; studies may be required to determine the safety of primarily beneficial species. Precautions should be taken that any entomopathogens capable of severely affecting beneficial arthropods are eliminated prior to release of the imported biological control agent in the United States.

The degree of risk involved as to potential detrimental effects of a natural enemy of a pest that may also attack non-target organisms (as in b, c and d above) should be weighed against the potential beneficial effects of the organism proposed for release. Emphasis should be placed on obtaining information needed in these cases from field studies in the country of origin, as much as possible, rather than on laboratory tests which may be misleading.

III. Initial Importation of Foreign Arthropod Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests.

Research workers should obtain as much pertinent information as practical concerning foreign biological control agents proposed for importation prior to their shipment to the United States. This information should include, if possible, an identification of the organism and its host(s)/prey, and pertinent biological information based on literature reviews and field observations, to assess the potential usefulness and safety of the candidate biological control agent.

Precautions as indicated in this Section of these Guidelines are designed to provide for the safe shipment and receipt of all foreign arthropod biological control agents for arthropod pests, regardless of the amount of preliminary information obtained overseas. Additional information may be required to be accumulated overseas and/or in quarantine prior to clearance of the biological control agent for release from quarantine.

In connection with overseas studies and explorations, it is recommended that Bartlett and van den Bosch (1964) be studied.

All potential arthropod biological control agents for arthropod pests shipped to the United States from foreign sources must: 1) have appropriate APHIS shipping permit labels affixed to the outside of the packages; 2) be shipped in containers meeting certain specifications; 3) be accompanied by specified documentation; and 4) be routed to and received and opened in designated approved primary quarantine facilities (see Section IV), with certain exceptions.

Inclusion of host plant or host arthropod material, soil, or dung, in shipments from foreign sources will be limited to those cases in which such inclusion is a necessity. Should potentially useful organisms and/or host material not covered by APHIS permits or authority be received in quarantine, APHIS should be notified after positive identification is made for post-shipment approval.

A. Approvals, Permits, and Shipment Labels for Importation.

1. General Procedures.

a. For arthropods for control of arthropod plant pests.

An APHIS permit and shipment labels for individual shipments or series of shipments of parasites and predators of plant pests from foreign areas shall be requested by the intended recipient or the shipper by completion of Section A of PPQ Form 526 (Attachment 1). [NOTE: THOUGH THE PPQ 526 IS THE CURRENTLY ACCEPTED FORM FOR OBTAINING APHIS-PPQ PERMITS, IT IS PROPOSED THAT A SIMILAR FORM SPECIFICALLY DESIGNED FOR BIOLOGICAL CONTROL ORGANISMS NOT DEEMED TO BE PLANT PESTS BE DEVELOPED BY PPQ (OR ARS) FOR USE BY ARS IN OBTAINING PERMITS FOR IMPORTATION AND INTERSTATE SHIPMENT OF SUCH BENEFICIAL ORGANISMS (PERHAPS FOR PURE CULTURES ONLY), IN PLACE OF THE PPQ-526; SEE ATTACHMENT 2.] Particularly important information to be included on this form are indications of any host material (plant or arthropod) to be included in the shipments, if any, the quarantine facility to which the shipments are to be sent, and the intended final destination of the parasites or predators. Arrangements must be made with the designated Quarantine Facility for quarantine receipt and handling and transshipment well in advance of intended importations. See Attachment 3 for list of approved quarantine receiving facilities, and Section 2 below for special procedures for overseas laboratories and explorations.

The application (PPQ Form 526) should be sent to the regulatory official of the State in which the quarantine receiving facility is located, with a request that Section B of the form be completed and the form be forwarded to APHIS-PPQ. See Attachment 4 for list of the addresses and telephone numbers of State and Territorial regulatory officials.

Before PPQ acts on the permit application, they will consult with pertinent taxonomists of the SEL and/or other organizations, personnel of the pertinent Quarantine Facility, and State and other regulatory officials as warranted. [NOTE: THE FOLLOWING STATEMENT IS RETAINED PENDING ACTION BY ARS, APHIS, AND OTHER AGENCIES.] At this time, the BCAC (see Section V.B) may also be consulted by PPQ. [END OF STATEMENT] After these consultations, PPQ will either issue a permit for the importation, deny the request, or request additional information prior to making a decision.

The permit consists of the completed PPQ Form 526 indicating PPQ approval and any special stipulations in Section C of the form. If importation is approved, PPQ will send the permit to the applicant, with copies to the appropriate Quarantine Facility and State regulatory official and to the BCDC. PPQ will also send appropriate shipment permit labels to the applicant for forwarding to the shipper. The shipment label will be placed on the outside of each shipment package to facilitate passage of the shipment through the mail or customs. The shipment labels indicate PPQ authorization of the shipment.

These permits and shipment labels are generally valid only for initial receipt of shipments in quarantine facilities. See Section V.C of these Guidelines for procedures for obtaining approvals for interstate shipments from quarantine facilities and for field release of parasites and predators. Supplies of PPQ Form 526 permit application are available from APHIS-PPQ or ARS-BCDC.

b. For arthropods for control of arthropod medical and veterinary pests.

An APHIS permit and shipment labels for individual shipments or series of shipments of parasites, predators, and competitors (e.g., dung beetles) of medical and veterinary pests from foreign areas shall be requested by the intended recipient or the shipper by completion of VS Form 16-3 (Attachment 5). Particularly important information to be included on this form are indications of any host material (plant, arthropod, or dung) to be included in the shipments, if any, the quarantine facility to which the shipments are to be sent, and the intended final destination of the parasites, predators, or competitors. Arrangements must be made with the designated Quarantine Facility for quarantine receipt, handling, and transshipment well in advance of intended importations. See Attachment 3 for a list of approved ARS quarantine receiving facilities, and special procedures for overseas laboratories and explorations discussed in Section 2 below.

There are special requirements for importation of dung-breeding Coleoptera from countries or areas in which pathogens or parasites known to be dangerous to the livestock industry of the United States are prevalent. In order that the livestock industry be given adequate protection from possible infection with exotic pathogens or parasites, procedures discussed in Section B.3 below must be followed. Requirements are less stringent for shipments of dung-breeding Coleoptera from countries where pathogens or parasites known to be dangerous to the U.S. livestock industry are absent.

There are also special requirements in cases where host/prey arthropods known to be vectors of human pathogens must be imported with their natural enemies. For information about these requirements, ARS personnel must contact the Foreign Quarantine Program, Centers for Disease Control, PHS, USDHHS, Atlanta, GA 30333, or PHS Quarantine Stations at U.S. ports of entry.

The permit application (VS Form 16-3) should be sent to VS, at the address shown on the form. Before VS acts on the permit application, they will consult with pertinent taxonomists of the SEL and/or other organizations, personnel of the pertinent Quarantine Facility, and State and other regulatory officials as warranted. [NOTE: FOLLOWING STATEMENT RETAINED PENDING ACTION BY ARS, APHIS OR OTHER AGENCIES.] At this time, the BCAC (see Section V.B) may also be consulted by VS. [END OF STATEMENT] After these consultations, VS will either issue a permit (VS Form 16-3a) for the importation, deny the request, or request additional information prior to making a decision.

If importation is approved, VS will send the permit to the applicant, with copies to the appropriate Quarantine Facility and State regulatory official and to the BCDC. VS will also send appropriate shipment permit labels to the applicant for forwarding to the shipper. The shipment label will be placed on the outside of each shipment package to facilitate passage of the shipment through the mail or customs. The shipment labels indicate VS authorization of the shipment.

These permits and shipment labels are generally valid only for initial receipt of shipments in quarantine facilities. See Section V.C of these Guidelines for procedures for obtaining approvals for interstate shipments from quarantine facilities and for field release of parasites, predators, and competitors. Supplies of VS Form 16-3 permit application are available from APHIS-VS or ARS-BCDC.

2. Special Permit Procedures for Importation: Overseas Biological Control Laboratories and Explorations.

APHIS and/or ARS [PENDING ACTION BY APHIS AND ARS ON NEW PERMIT APPLICATION FORM AND PROCEDURES] can issue shipment labels without issuance of specific permits for importation of parasites and predators, under special circumstances. Generally, such issuance will be made only to ARS overseas biological control laboratories, or other well-known overseas laboratories, or biological control workers conducting extensive overseas biological control explorations. These shipment labels are for use for shipments only of biological control agents without animal or plant host or other material. If plant or arthropod host material is expected to be included in the shipments, a formal permit from PPQ or VS is required, following the general procedures as discussed in Section III.A.1. [NOTE: STATEMENT RETAINED PENDING ACTION BY ARS AND APHIS.] Furthermore, permit labels will be issued for shipments only to quarantine facilities in States in which the appropriate regulatory officials have agreed to such special procedures under a signed tripartite Compliance Agreement (see Section IV.B). [CLOSE OF STATEMENT]

A supply of such shipment labels will be provided in response to memoranda explaining in appropriate detail the purposes for which the shipments will be made, the Quarantine Facility to which the shipments will be sent, and the type of material (and their host/prey) to be shipped. PPQ, VS, and ARS will consult with personnel of the pertinent quarantine facilities, SEL, and others as required.

PPQ or VS will provide the BCDC and the appropriate State regulatory officials with a record of shipment labels issued, and the recipients of the labels will furnish PPQ or VS, BCDC, and State regulatory offices with a record of material imported under these special procedures on a periodic basis (see Section IV.D. of these Guidelines). [FOLLOWING STATEMENT RETAINED PENDING ACTION BY ARS AND APHIS.] ARS will provide to PPQ or VS a record of shipment labels it issues under these special procedures. [END OF STATEMENT]

3. Shipments to Non-Quarantine Facilities.

The requirement for initial receipt in approved quarantine facilities may be waived in cases of some shipments, generally pure cultures of natural enemies, entering the United States from Canada and Mexico, and in certain other cases as determined by PPQ. However, a permit for such importations is still required, which will include consultation with appropriate research and regulatory personnel (see Section III.A.1).

B. Shipping Procedures, Containers, and Problems.

1. General Considerations.

All foreign organisms shipped to the United States or later shipped interstate must be shipped in containers meeting USDA standards, and must be shipped with APHIS (and as necessary PHS) approval. Prior notification of impending shipments should be made to the receiving quarantine facility to facilitate planning for space in maximum security and other preparations for receipt of the shipment. Likewise, notification should be made to port inspectors or customs at ports of entry to facilitate clearance of packages. If entry of host plant material is required, it must be destroyed in quarantine. Entry of exotic arthropod host/prey material must be restricted as much as possible. If entry of such organisms is required, they must be destroyed in quarantine.

Research workers should obtain as much pertinent information as practical concerning foreign biological control agents proposed for importation prior to their shipment to the United States. This information should include, if possible, an identification of the organism and its host(s)/prey, and pertinent biological information based on literature reviews and field observations, to assess the potential usefulness and safety of the candidate biocontrol agent. Precautions are designed to provide for the safe shipment and receipt of all foreign arthropod biological control agents for arthropod pests, regardless of the amount of preliminary information obtained overseas. Additional information may be required to be accumulated overseas and/or in quarantine prior to clearance of the biological control agent for release from quarantine.

Should potentially useful organisms and/or host material not covered by APHIS permits or authority be received in quarantine, APHIS should be notified after positive identification is made for post-shipment approval.

2. Shipping Containers.

Shipping containers will vary according to the requirements of the material to be shipped. However, in all cases, material from foreign sources must be shipped in a container within a container, both of sturdy construction and capable of being sealed. This precaution is required to reduce the risk of escape of natural enemies, host/prey, or other organisms should the shipment package be crushed or otherwise damaged in transit. The outer container should be of sturdy impact-resistant material and be enclosed in finely-woven, securely sealed, heavy cloth or canvas, or heavy wrapping paper. The inner container may be of metal, wood, heavy glass, cardboard, or plastic, and should be securely sealed; this container may also be wrapped and sealed in paper, tightly-woven cloth, or other type sealing materials. Approved packing materials necessary for cushioning the inner package within the larger container, include absorbent cotton or processed cotton free of cottonseed, cellulose or plastic materials, excelsior, paper or paper products, sponge rubber, or vermiculite. See Bartlett and van den Bosch (1964) and Boldt and Drea (1980) for other information concerning packaging of beneficial organisms for shipment.

The outer package should prominently display the appropriate shipment authorization label and institutional identification, including the address and telephone number of the contact person at the receiving institution.

Both the inner and outer container and all packing material will be destroyed or otherwise treated by incineration, heat or other methods, after contents are removed in the Quarantine Facility, in such a manner that any included pathogens or other organisms are destroyed. Specific procedures will be indicated in Quarantine Operational Procedures (see Section IV.C.2).

3. Special Problems Associated with the Importation of Beneficial Arthropods Inhabiting Animal Dung.

a. Parasites of dung-developing Diptera.

Insect parasites of dung-breeding flies can be introduced if the parasites are reared on material (generally dipterous pupae) that does not present a risk of introducing exotic pathogens.

b. Predators of dung-developing Diptera.

Insect predators can be introduced by one of two approved methods. One method allows predators to be colonized in the country of origin. A sample of beetles from each colony of these predators can then be sent to the USDA-ARS Plum Island Animal Disease Center (Plum Island, NY) for testing to be sure they are free of exotic pathogens. If clean, the remainder of the colony or their offspring could then be imported. The other method involves surface sterilization of the eggs of the predator in 3% formalin (see Section 3.c below for details). Eggs from progeny of identified predators introduced using either of these methods can be surface-sterilized and removed from quarantine.

In practice, dung-inhabiting predators (Staphylinidae and Histeridae) are generally collected from cattle or other dung dropped in the country of origin. These predators are identified and separated by species, and 4-5 pairs of each candidate species are placed in individual rearing containers with 1-2 moist paper towels. Eggs and/or larvae from a colony of house flies are then placed on the paper towels. The parent beetles are removed each day and placed in similar containers with paper towels and house fly eggs/larvae while the remaining towels and containers are examined for staphylinid or histerid eggs. Eggs are collected and processed by the surface-sterilization procedure.

Because of the cannibalistic habits of the larval stages, eggs of predators are placed in individual vials for shipment. An egg is placed on a layer of moist paper napkin or towel in the bottom one-fourth of each vial. An additional layer of paper is added to fill approximately two-thirds of the vial. Frozen eggs and larvae from a house fly colony are then placed on top of this layer of paper to provide food for the larva if the egg hatches en route. A small wad of cotton is used to plug the vial. The cotton plug is taped to the vial so that about one-half of the surface area of the plug is not covered by tape in order that air in the vial can be exchanged but the larva cannot escape. These vials are then wrapped in paper napkins and placed in plastic containers of various sizes with screen lids. The containers are then placed in shipping cartons with plastic shipping materials.

c. Competitors of dung-developing Diptera

There are two ways to bring exotic species of dung-burying beetles into the U.S. according to regulations set by APHIS VS: (1) If the country of origin is free of exotic livestock diseases, adult beetles can be imported; (2) If the country of origin has one or more exotic livestock diseases present, then only eggs of beetles that have gone through a special cleansing procedure can be brought into the U.S.

The second method requires that parent dung beetles be bred in culture in the country of origin. Eggs from these beetles must be removed from the brood balls made of cattle or other dung, washed several times in water, rinsed in detergent water, immersed in 3% formalin for 5 minutes, and then rinsed with sterile water. These processed eggs must then be packed in moist peat moss, previously shipped from the U.S. in sealed containers, prior to shipment to quarantine facilities in the U.S. When received in quarantine, the eggs must be transferred to specially-prepared dung balls from U.S. sources. It is recommended that a qualified U.S. scientist directly supervise all phases of the project, particularly those conducted in the country of origin. [NOTE: THE REQUIREMENT FOR U.S. PRESENCE AT OVERSEAS LOCATIONS DRASTICALLY REDUCES THE NUMBER OF BEETLE EGGS AND CANDIDATE BEETLE SPECIES THAT CAN BE SHIPPED BECAUSE OF TRAVEL RESTRICTION, ETC. THUS, THE FOLLOWING STATEMENT IS RETAINED PENDING DISCUSSION WITH AND DECISIONS BY APHIS-VS.] However, the designated Quarantine Officer responsible for importations will have the authority to recommend that, in cases of cooperation with established overseas entomological laboratories, the senior entomologist at such overseas laboratories be authorized to conduct "country of origin" phases without direct supervision by U.S. scientists. [END OF STATEMENT]

Because this method often results in eggs hatching en route and death of larvae due to lack of food, another shipping procedure has been approved by VS, using freeze-dried "donor" brood cells that provide food for larvae emerging during shipment. This procedure is the same as the above procedure except that beetle eggs are placed in "rehydrated" donor brood cells after the cleaning and surface sterilization processes. The donor brood cells, made with cattle dung by beetles in the U.S., are freeze-dried, sent to the country of origin, rehydrated and implanted with eggs of candidate species of beetles, then packed in containers with moist, autoclaved peat moss and shipped to the U.S. Upon arrival in quarantine, the donor brood cells are removed from the peat moss and placed in containers of soil to await adult emergence.

C. Documentation of Importation.

Because classical biological control projects involve the introduction, release, and establishment in the United States of organisms from other countries, it is important that importations and releases be properly and thoroughly documented.

All shipments from foreign or overseas sources, or shipments from domestic sources that require quarantine receipt, should be accompanied by an AD Form 941 (Attachment 6), with Section I of the form completed and copies distributed in accordance with instructions on the form. This form provides source, culture, and other information for the recipient of the shipment, and feedback information for the shipper on the results of the shipment. All ARS and other overseas laboratories and personnel engaged in shipping biological control agents to the United States, and all approved U.S. or territorial quarantine

facilities, will be provided by the BCDC with a supply of these forms, and the forms will be issued by them or by BCDC to explorers or other overseas shippers when notified by PPQ or VS of the issuance of an importation permit or shipment labels for individual shipments.

A field set booklet, the AD-941-1 (essentially Section I of the AD-941), is available for use in the field by foreign explorers; one copy of the AD-941-1 form should accompany each shipment sent to quarantine facilities. In cases where shipments are received without AD-941 type documentation, the receiving Quarantine Facility will be responsible for completion of Section I of the AD-941 form with information to be obtained from the shipper or other sources.

Whenever possible, collectors and shippers should retain properly prepared specimens of the natural enemies shipped and of their host/prey, to serve as voucher specimens. Collectors and shippers should provide receiving quarantine facilities and the BCDC with information regarding the identity of the natural enemy shipped and/or its host/prey that may in time differ from that given originally on the AD-941 form. See Section V.E of these Guidelines for more information concerning voucher specimens.

IV. Quarantine (Containment) Facilities, Personnel, and Operational Procedures.

All ARS facilities charged with responsibility for the quarantine receipt and clearance in the United States of foreign arthropod biological control agents for arthropod plant or medical and veterinary pests must conform to certain required physical qualifications. [NOTE: THE FOLLOWING STATEMENTS ARE RETAINED PENDING DECISIONS BY ARS AND APHIS.] The facility must operate under a Compliance Agreement or Memorandum of Agreement between ARS, APHIS, pertinent State quarantine regulatory agencies, and appropriate non-governmental institutions (e.g., universities). The Compliance Agreement, which will be monitored by APHIS, will stipulate certain operational and documentation procedures required for operation of the facility in the quarantine receipt and handling, and transshipment and field release, of foreign arthropod biological control agents. [CLOSE OF STATEMENTS]

A. Type of Facilities Required for Initial Quarantine Receipt of Foreign Arthropod Biological Control Agents for Arthropod Plant and Medical or Veterinary Pests.

All ARS facilities to be engaged in primary quarantine receipt of foreign arthropod parasites, predators, and competitors are required to be inspected and approved for such purposes by authorized representatives of PPQ, and VS or PHS as appropriate, prior to approval for operation. The inspection will be conducted to insure that adequate physical safeguards exist to minimize or eliminate the possibility of escape of arthropods from the Quarantine Facility.

These physical safeguards shall include:

- 1) A double-door anteroom entryway with doors of arthropod escape-proof design (with gaskets to form a seal at all door edges, frame, and floor), and both equipped with automatic closers or electrical interlocking devices; first door locked at all times.
- 2) A warning sign outside of first entry door stating, e.g., "Quarantine Area, Only Authorized Personnel Permitted Entry."
- 3) Sealed or otherwise arthropod- and rodent-proof floors, walls, ceilings, windows and doors; all pipes, conduits, etc., penetrating ceiling, walls, or floors, must be carefully sealed with silicon

caulking at both inside and outside surfaces; in anteroom, use black paint for walls, doors, and ceilings; for walls in rest of quarantine use white, epoxy paint, gray for floors; windows, if any, must be triple-glazed and shatter proof.

4) Sealed or otherwise insect- and mite-proof electrical system, including sealed floor and wall plugs, switches and lights.

5) Heating, cooling, and exhaust systems, preferably closed air systems, fitted with filters adequate to prevent escape of insects and mites. A pressurized air system, with positive pressure in noncontainment areas and negative pressures in containment areas, is desirable.

6) Plumbing system designed to prevent escape of insects, mites, and other arthropods, including adequate screening of floor drains and other accessible drain lines. A trap where waste water from the Quarantine Facility can be sterilized or otherwise treated is highly desirable.

7) Direct access in quarantine to incineration or heat treatment systems for destruction or sterilization purposes.

8) Traps effective for various arthropod species placed in anterooms and any other strategic possible escape routes.

9) Provision for maximum security area for initial opening of incoming packages of exotic material is highly desirable.

10) Provision for special confinement of individual arthropod species to separate cages, chambers or containers within the quarantine area.

11) Means of providing limited access to quarantine area only to workers directly assigned to quarantine program (see also 1 above).

12) Intercommunication system to allow communication with quarantine personnel without need to enter or leave quarantine area.

13) Provision for shower room and/or for change of clothing in quarantine area; this may be considered optional.

14) Sealed emergency door with panic hardware, wired to an alarm, with sign "Emergency Exit Only;" fire warning alarms in quarantine.

If foreign host/prey arthropods known to be vectors of human pathogens must be imported with their natural enemies, special physical facility requirements may need to be met. For information about these requirements, ARS personnel must contact the Foreign Quarantine Program, Centers for Disease Control, PHS, USDHHS, Atlanta, GA 30333, or PHS Quarantine Stations at U.S. ports of entry.

For additional information on Quarantine Facility requirements and design, see Section 3 - "Quarantine Facilities" in Leppla and Ashley (1978).

B. Approval of Quarantine Facilities.

1. Inspection and APHIS approval.

If physical safeguards are deemed to be adequate after inspection by PPQ, and VS or PHS as necessary, or following the rectification of any deficiencies found during inspection, APHIS (PPQ and/or VS) will issue a dated and renewable certificate indicating approval for quarantine operation. This certificate should be prominently displayed by the approved Quarantine Facility. APHIS officials will conduct periodic and unannounced re-inspections of the facility to assure the continuing adequacy of these physical

safeguards. State regulatory officials are also authorized to inspect the facilities upon their request.

ARS and other facilities currently authorized to serve as quarantine facilities for arthropod parasites, predators, and competitors are listed in Attachment 3. No other ARS facilities are authorized to receive arthropod parasites, predators, and competitors directly from foreign sources, with some exceptions as authorized by PPQ or VS (see Section III.A.3).

The approved ARS quarantine facilities will provide address labels and pertinent shipping instructions, including instructions to airline, post office, and customs officials as appropriate, to ARS and other overseas laboratories and personnel upon request, or to the permittee (applicant) upon notification of issuance of a permit for shipment to be received at those facilities (see Section III.A.1).

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY ARS AND APHIS.]

2. Compliance Agreements or Memoranda of Agreement.

As noted in these Guidelines, ARS quarantine facilities will be required to operate under a Compliance Agreement or Memorandum of Agreement between ARS, APHIS-PPQ and -VS as appropriate, pertinent State quarantine regulatory agencies, and appropriate non-governmental institutions (e.g., universities). The specific provisions of these Compliance Agreements or Memoranda of Agreement authorizing Quarantine Facility operations, which will vary depending on the location and type of each facility, will be determined by PPQ (and/or VS) in consultation with pertinent State regulatory officials and ARS line and staff officials and research personnel. These provisions will include:

- 1) Approval of the physical safeguards of the Quarantine Facility, as discussed in Section IV.A. above.
- 2) Agreement for Quarantine Facility adherence to quarantine importation permit procedures as outlined in Section III.A-B of these Guidelines (insofar as Quarantine Facility involvement in such procedures is concerned), and for adherence to transshipment and release procedures as may be agreed upon, as outlined in Sections V.A and C of these Guidelines.
- 3) Approval of specific quarantine operational procedures for the Quarantine Facility, as summarized in Section IV.C.2 of these Guidelines, including safety considerations and precautions to be made in quarantine handling and clearance for release from quarantine of arthropod foreign parasites and predators as discussed in Section V of these Guidelines.
- 4) Agreement for Quarantine Facility compliance with documentation procedures to be agreed upon, as outlined in Sections III.C, IV.D, and V.C-D of these Guidelines.
- 5) Any other specific procedures or regulations to be followed, or specific restrictions on types of materials to be received or shipped, as may be required by regulatory agencies of the State in which the Quarantine Facility is located.
- 6) Designation of specific Quarantine Officer for the Quarantine Facility, who in conjunction with an appropriate administrative official, will have exclusive control over quarantine actions, including those authorized by APHIS, and be responsible for assuring compliance as noted in items 2-5-above.

These Compliance Agreements or Memoranda of Agreement must be approved by the appropriate ARS and PPQ and VS officials, and the pertinent State regulatory agency, and will be

monitored by PPQ and VS officials to the extent they may deem necessary. State regulatory officials are also authorized involvement in monitoring of these agreements.

[END OF SECTION]

C. Quarantine Personnel and Operational Procedures.

1. Quarantine Personnel.

Each Quarantine Facility must have a designated Quarantine Officer. Quarantine Officers will be appointed by the appropriate ARS official after consultation with the NPS, Research Leaders or Laboratory Chiefs, and Area or Center Directors. Quarantine Officers have a great deal of responsibility, and must exercise their duties at a high level of excellence. Errors in judgement potentially could have serious consequences for U.S. agriculture. The traits and attitudes of a good Quarantine Officer have been described by Fisher (1964). The Quarantine Officer will be thoroughly trained in arthropod classification and morphology, quarantine philosophy, and quarantine operational procedures. New Quarantine Officers should undergo apprenticeship training which allows for hands-on work under the supervision of an experienced Quarantine Officer. The Quarantine Officer is responsible for assuring that applicable quarantine procedures are followed. Specific responsibilities include:

- a) Adherence to permit, documentation, voucher, and other specifically required procedures;
- b) Proper confinement of all organisms in the quarantine areas;
- c) Handling of these organisms, alone or by coworkers assigned to the quarantine program, in a manner to prevent escape of organisms;
- d) Obtaining authoritative identification of the organisms;
- e) Authorizing the release of organisms from quarantine after screening; and
- f) Packaging and shipment of organisms in such a manner as to prevent their escape during transport.

Ultimate responsibility for the release of organisms from the Quarantine Facility rests with the Research Leader of the facility, who in certain cases may be designated Quarantine Officer.

Other personnel assigned to the quarantine program will be limited in number, and thoroughly instructed in the quarantine operational procedures (QOP). Lists of personnel authorized permanent or temporary access to the quarantine area will be prepared and prominently posted. All other personnel will be denied access to the quarantine areas unless accompanied by the Quarantine Officer or his designated representative.

2. Quarantine Operational Procedures (QOP).

In order to minimize the risks associated with the introduction of exotic organisms, it is important that quarantine personnel not only be highly skilled and well trained, but that they follow well defined standard operating procedures to prevent unwanted introductions.

Each ARS Quarantine Facility will prepare specialized quarantine operational procedures (QOP), which may differ depending on the location, primary mission, physical construction, and staffing of the facility. These operational procedures will be approved by appropriate ARS line and staff

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officials, and by APHIS and State regulatory officials prior to authorizing operation of the facility as a Quarantine Facility for receipt of foreign arthropod biological control agents for arthropod plant pests and/or medical and veterinary pests, whichever may be the case.

The approved QOP will be posted near the entrance of the quarantine area of the facility. APHIS officials will conduct periodic unannounced inspections of the facility to ascertain that these procedures are being followed, and State regulatory officials may also conduct such inspections.

Quarantine operational procedures must include reference to the following five categories:

a. Specific permit and approval procedures for the facility.

1) Description of the permit and approval procedures for importations (see Sections III.A [FOLLOWING PHRASE RETAINED PENDING DISCUSSION WITH APHIS-VS] and the note concerning quarantine officer involvement regarding approving shipments of dung beetles, Section III.B.3) specific to the facility, to include provision for handling unsolicited shipments arriving without proper permits or approvals, and for following other specific procedures as may be stipulated by local regulatory officials, etc.

2) Provisions for assuring maintenance of quarantine conditions for the facility, including limited access to quarantine areas, requirements for protective clothing, etc., in order to retain authority for continued direct receipt of foreign material.

b. Provisions for receipt, examination, and processing of incoming shipments, to include:

1) Provision for opening of incoming shipments only in special containment areas within quarantine.

2) Description of means of destruction or sterilization of shipping containers and packing material within quarantine.

3) Description of means for quarantine screening of imported material and for elimination of inadvertently, inappropriately, or necessarily included organisms such as arthropod or plant hosts, secondary parasites, or plant or insect pathogens.

For parasites, this will involve holding all material received as immatures and/or in hosts in quarantine until adult parasites and/or hosts emerge, and the meticulous separation of emerging species for identification. Such separation is also required, of course, when parasite adults are received in quarantine. In certain cases, rearing of parasites in quarantine to at least an F_1 laboratory generation may be deemed desirable (see also Section V.A).

For predators of plant pests, the species must be cultured at least to an F_1 stage (egg, larval, or adult) to eliminate parasites or pathogens; in some cases, such culture of predators may be conducted overseas or in secondary quarantine facilities (see Section V.A).

Predators of dung-inhabiting Diptera are generally shipped as eggs, but hatch frequently occurs en route. Upon receipt in quarantine, the predator larvae should be placed in individual rearing containers with cattle dung and fly eggs from U.S. sources. Adults reared from these larvae should be sexed and 4-6 pairs placed in rearing containers for culture/colonization. After adequate numbers of

adult beetles of a candidate species begin ovipositing, eggs can be removed from quarantine following surface-sterilization (see Section III.B.3).

Competitors of dung-developing Diptera from countries free of exotic livestock diseases can be imported as adult beetles. These must be cultured to an F₁ stage to eliminate parasites or pathogens. Competitors from countries having exotic livestock diseases must be imported as surface-sterilized eggs in moist peat moss or rehydrated freeze-dried "donor" brood cells (see Section III.B.3). Eggs from the former are transferred to specially prepared dung balls from U.S. sources, and eggs from the first generation to breed in the U.S. are surface-sterilized prior to being released from quarantine. Donor brood cells shipped to the U.S. are removed from peat moss and placed in containers of soil to await adult emergence. Eggs produced by these adults are surface-sterilized prior to being released from quarantine. It is recommended that quarantine facilities conducting importation, quarantine, release, and interstate movement of dung-breeding Coleoptera, or other agents requiring dung for culture, have all cattle used for production of such dung for use in rearing procedures or for providing as donor cells, tested for tuberculosis and paratuberculosis.

4) In all cases, all foreign plant, unwanted arthropod, and other host or habitat material must be destroyed in quarantine as soon as possible, and the QOP must indicate specific means of such destruction, and stipulate that only healthy domestic host material will be used if required to maintain cultures of parasites, predators, or competitors in quarantine.

- c. Notification of possible taxonomic problems and procedures for obtaining taxonomic assistance.

Means must be described in the QOP for obtaining rapid authoritative identification of arthropod species received in quarantine. Appropriate specialists should be consulted in advance for proper specimen preparation and submittal procedures. Whenever possible specimens of original or F₁ generation material should be submitted for identification of the initially received material. Identifications should be submitted to the appropriate taxonomic specialist for determination to the lowest possible taxon. Quarantine Officers may request advice from SEL, the principal USDA center for arthropod identifications, in establishing their facility's procedures for obtaining identifications. See Steyskal et al. (1986) for techniques for specimen preparation and Forms ARS-748 and 748A (Attachment 7) for procedures for submitting specimens to SEL for identification.

- d. General procedures for host specificity and other quarantine testing.

The QOP should include a detailed protocol to be followed prior to consignment of organisms from maximum quarantine containment area for further testing as required, or prior to the decision to consign organisms from quarantine for further shipment or field release. This protocol should include consideration of the known or tested host range and relationships of the species or of the taxonomic group to which it belongs, its potential effect on other beneficial organisms, adequacy of safeguards for elimination of secondary parasites or parasites of predators, adequacy of taxonomic identifications, and other safety considerations listed in Section II.B of these Guidelines.

Although the element of risk involved in the importation of arthropod biological control agents is relatively low (see remarks in Section I of these Guidelines), quarantine protocols and procedures are devised in order to prevent the concurrent accidental introduction of undesirable organisms. For introductions of arthropod parasites, predators, or competitors, these risks involve plant pests, hyperparasites, enemies of beneficial or other desirable non-target species, and disease agents, whether of plants, animals, or man.

Plant Pests -- There should be evidence that the candidate biological control agent itself is not a plant feeder or otherwise a potential plant pest; if one stage is phytophagous (e.g., some predators), the extent of potential damage and potential plant host range should be determined, as well as any potential for vectoring plant diseases.

Hyperparasites -- Hyperparasites, or secondary parasites, are species which attack and develop on immatures of other parasites/parasitoids. Provision is required for the elimination of all obligatory hyperparasites. Facultative hyperparasites should be eliminated except under circumstances where potential benefits can be shown to outweigh potential detriments.

Enemies of Non-Target Species -- The potential effect of the biological control agent on non-target organisms (e.g., biological control agents for weeds, predators, pollinators, endangered species, etc.) should be considered. In the vast majority of cases this is not an issue, because biological control workers search for and import arthropod natural enemies exhibiting a high degree of host or prey specificity, for experience has shown that these are generally the most efficient natural enemies in suppressing pest populations (Doutt and DeBach, 1964). Sometimes, mildly or broadly polyphagous species, often referred to as generalists, are found overseas which appear to be important mortality factors in the population dynamics of the target pest. In these cases, the potential for attacking non-target organisms should be assessed, but testing should be limited to those species (or closely related species) for which there is concern.

Disease Organisms -- In some rare cases, there is a possibility that a natural enemy could be a vector of plant pathogens. Tests may be needed to (1) determine the extent of potential damage and (2) assure the elimination of foreign plant pathogens.

Potential Medical or Veterinary Problems -- Tests may be deemed desirable in the case of certain predators of plant pests to determine whether they are capable of harming humans or animals and the likely extent of such action. This same safety consideration also applies to coleopterous parasites, predators, and competitors associated with dung, and other natural enemies of medical and veterinary arthropod pests, with the additional consideration of potential entry of vectors of animal or human pathogens.

If, following the aforementioned tests, any doubts remained concerning the propriety of release of the organism from quarantine, the matter could be placed for consideration before a panel of biological control scientists (see Section V.B.).

See Sections V.A-C of these Guidelines for discussion of quarantine protocols addressing these risks.

e. Other quarantine aspects to be addressed in the QOP.

- 1) Means for quarantine storage, for overwintering or other reasons, of the imported organisms.
- 2) Procedures for shipment from quarantine, including proper packaging, and permit and approval procedures (see Section V.C of these Guidelines).
- 3) Documentation procedures (see Sections III.C, IV.D, and V.D of these Guidelines).
- 4) Voucher procedures (see Section V.E of these Guidelines).
- 5) Provisions for monitoring of the QOP by the Research Leader or Laboratory Chief of the Quarantine Facility.

D. Documentation of Receipt of Imported Material.

The Quarantine Officer of each APHIS-approved ARS Quarantine Facility is responsible for completion of Sections II and III of AD Form 941 (Attachment 5), which is to accompany each shipment of foreign material received (see Section III.C of these Guidelines), and for filing and distribution of the copies of this form according to instructions on the form. The Quarantine Officer is also responsible for assuring that these forms are included in all incoming shipments, or for their preparation if not so included. In cases in which the shipper has used the AD-941-1, the Quarantine Officer must complete Sections I-III of a full AD Form 941.

A record of all shipments and species received in the Quarantine Facility will be periodically provided to BCDC, PPQ (and VS if appropriate), and the pertinent State regulatory agency. (See also Section V.D for additional records to be provided by the Quarantine Facility).

The Quarantine Officer should retain properly prepared specimens of incoming natural enemy parent or F_1 material (and of original host/prey material, if available) to serve as vouchers representing material received in quarantine. See Section V.E for additional information concerning voucher specimens.

V. Quarantine Consignment, Interstate Shipment, and Field Release of Foreign Arthropod Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests.

After the proper importation approvals and permits have been obtained, the candidate natural enemy has been authoritatively identified, hyperparasites or other undesirable organisms eliminated, shipping materials and residues properly destroyed, any required testing completed, and overwintering or other problems overcome, a decision must be made as to whether or not the organism should be consigned from quarantine. A number of factors go into making this decision: safety and environmental considerations, the chain of responsibility, and provisions for meeting federal and state regulations. The disposition of organisms consigned may be likewise controlled. Approval might be obtained for field release, shipment to a secondary quarantine facility, interstate shipment to cooperators, export to another country, or a combination of these. Procedures and considerations required prior to consign/release from quarantine are included in the facility's Quarantine Operational Procedures (QOP) [FOLLOWING PHRASE RETAINED PENDING ARS AND

APHIS DECISIONS.] and Compliance Agreement or Memorandum of Agreement [END OF PHRASE] approved by APHIS.

A. Quarantine Consignment.

1. Decision-Making at the Quarantine Facility Level.

The ultimate responsibility for the consignment of an organism from quarantine rests with the Research Leader or Laboratory Chief of the ARS Quarantine Facility, although authority for making this decision may be delegated to a designated Quarantine Officer under certain circumstances. Procedures and considerations required prior to consignment from quarantine are included in the Quarantine Operational Procedures document [FOLLOWING PHRASE RETAINED PENDING DECISIONS BY ARS AND/APHIS.] and Compliance Agreement or Memorandum of Agreement [END OF PHRASE] approved by APHIS (see Sections IV.B-C and V.A-E of these Guidelines).

The Quarantine Officer is responsible for: 1) Assurance that safety considerations (see Sections II.B and IV.C.2) are made prior to consignment of the organism from quarantine, or that proper arrangements are made for any additional testing deemed to be required; 2) Assurance that any necessary authorizations for field release and/or interstate shipment of the organism are obtained (see Section V.C below); 3) Documentation procedures involved following consignment from quarantine; and 4) Preparation of voucher specimens as appropriate.

It is important that all relevant safety and environmental considerations be taken into account so that responsible official(s) can make informed decisions as to whether or not a candidate species should be consigned from quarantine. All decisions to release from quarantine do not involve the same degree of risk. Depending upon the objective, the risks associated with the consignment/release of a candidate natural enemy from quarantine can be ranked in ascending order as follows: (1) shipment to another high security quarantine facility; (2) shipment to a secondary quarantine facility for further study; (3) transfer to a nonquarantine laboratory (at the same or another facility) for rearing or additional study with eventual release probable; and (4) direct field release by quarantine, or shipment to a cooperator for direct field release.

Included in the QOP, [FOLLOWING PHRASE RETAINED PENDING ARS AND APHIS DECISIONS.] which are an integral part of the Compliance Agreement or Memorandum of Agreement to be entered into between the ARS Quarantine Facility, APHIS, and the pertinent State regulatory agency, [END OF PHRASE] are detailed protocols to be followed prior to release of organisms from quarantine (see Section IV.C.2). These protocols include review, clearance, and testing procedures required prior to consignment/release of parasites, predators, and competitors from quarantine.

In general, approval for consignment from quarantine is given if the appropriate studies have been completed by the project scientists and, in the case of field release or interstate shipment, if the appropriate permits from State (if necessary) and Federal regulatory agencies have been obtained. It should be noted that the Quarantine Officer may not overrule regulatory agencies and release or ship the organism if the appropriate permits have not been obtained from State and/or Federal agencies.

2. Review and Clearance Procedures for Consignment/Release.

The first step in quarantine clearance procedures must be to obtain an authoritative morphological and/or biological identification of the organism, at least to generic level if possible (see Section IV.C.2.c). No live material with insufficiently known host relationships will be permitted to leave quarantine. The Quarantine Officer, with the pertinent researcher involved with the organism, will determine clearance for consignment of an organism from quarantine by means of a critical review of available ecological and biological information based on the taxonomic identification of the species and discussions with relevant knowledgeable experts, including taxonomists and biological control research workers. During this review, special attention will be made to the several areas of safety considerations listed in Sections II.B and IV.B.2 of these Guidelines. Based on this review of information and discussions, conclusions are reached by the Quarantine Officer in which the identified organism is assigned to one of four quarantine clearance categories:

Class A: The organism is considered dangerous or otherwise unsuited for continued experimentation. All material placed in this category must be destroyed in quarantine.

Class B: The organism is considered a potential biological control agent, but ecological, biological, or taxonomic data are missing, questionable, or need clarification. Material placed in this category is restricted to the primary Quarantine Facility for further study. See Section V.A.2 for further procedures.

Class C: The organism is considered a promising biological control agent, but specific additional studies are deemed necessary before field release is permitted. Material placed in this category may be given clearance for consignment or shipment to secondary quarantine facilities of such design as to prevent escape during conduct of the needed studies. Such consignment/shipment will be at the discretion of the Quarantine Officer of the primary Quarantine Facility, with the approval of APHIS. See Sections V.A.3 and C.3 for further procedures.

Class D: The organism is considered safe for field release in the U.S. Material placed in this category may be consigned to non-quarantine personnel of the Quarantine Facility for field release or shipped interstate following procedures stipulated under Section V.C.

3. Quarantine Testing.

Included in the several areas of safety considerations listed in Sections II.B and IV.C.2, is the need for information that may require testing of the organism under quarantine conditions. This includes the following considerations:

- a. Potential plant pests or vectors of plant pathogens.

This applies in the case of certain predators (e.g., Pentatomidae) or competitors (e.g., Aphodiinae), one stage of which are plant-feeders, and certain parasites ovipositing in hosts within plant tissue. Tests may be deemed desirable to (1) determine the extent of potential damage to plants and potential "host" range, and (2) assure the elimination of foreign plant pathogens. If the latter tests are deemed necessary, they must be conducted overseas or in adequate quarantine facilities.

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- b. Potential animal or human pests or vectors of animal or human pathogens.

This applies in the case of certain predators of plant pests. Tests may be deemed desirable to determine whether the potential predator is capable of harming humans or animals and the likely extent of such action. This same safety consideration also applies to coleopterous parasites, predators, and competitors associated with dung, and other natural enemies of medical and veterinary arthropod pests, with the additional consideration of potential entry of vectors of animal or human pathogens.

- c. Potential pests of beneficial or non-target invertebrates.

- 1) Potential hyperparasites: Some parasitic species may be known or suspected to act on occasion as facultative hyperparasites, i.e., secondary parasites. Tests may be required to determine the potential extent and effect of such action.

- 2) Potential parasites of beneficial species: If the exotic parasite attacks hosts in taxonomic groups that include primarily beneficial species (e.g., the Coccinellidae or important introduced weed-feeding arthropods), host specificity tests are required to determine the safety of beneficial species. These tests must be conducted in primary quarantine facilities or overseas.

- 3) Other such host specificity tests may be required to ascertain whether arthropod or other invertebrate species on Federal or pertinent State lists of rare or endangered species will be further endangered by the competitor, predator or parasite proposed for introduction.

- 4) In the case of biological agents for control of dung-breeding arthropods, the potential effect of the agent on other beneficial dung-breeding organisms may require some testing, some of which may best be conducted overseas.

Some of the information needed concerning organisms placed in Classes B and C (see Section V.A.1) may include data that must be accumulated by the tests indicated above. Emphasis, however, should be placed on obtaining such information from field studies in the country of origin, as much as possible, rather than relying solely on results of laboratory tests. Concomitant laboratory tests as needed may be performed either in the primary Quarantine Facility in which the material is initially received, or in secondary quarantine facilities (see Section V.A.3). This decision depends primarily upon the availability of adequate facilities, appropriately experienced personnel, and host/prey materials, and the approval of APHIS and pertinent State officials.

If, following quarantine testing of the organism, any doubt remains concerning the propriety of consignment of the organism from quarantine, the matter may be placed before a panel of biological control scientists [PHRASE RETAINED PENDING ARS AND APHIS DECISIONS.] and/or the BCAC (see Section V.B) [END OF PHRASE] for arbitration. It is important that any potential detrimental effects of a biological control agent proposed for release as may be indicated by such laboratory tests be critically weighed against the potential beneficial effects of the proposed release and the evidence obtained from field studies and published information concerning the biological control agent where it occurs in nature.

4. Secondary Quarantine Facilities.

As noted in Sections 1-3 above, some organisms may require the accumulation of additional information, including certain laboratory testing, prior to being cleared for release from quarantine or general field release, and some of these tests and studies can often best be conducted in secondary quarantine facilities. Such facilities must have a double-door entryway, sealed, screened, or no windows, and filtered air circulation, and otherwise be adequate to contain the organisms to be studied. Any other requirements will be determined in consultation with APHIS on an individual basis, depending upon the type tests and types of organisms to be studied under quarantine conditions. The facilities must be inspected and approved by PPQ or VS, as appropriate, and may be required have a designated Quarantine Officer and QOP.

Only authoritatively identified arthropod parasites, predators, and competitors assigned to Class C (see Section V.A.2) by a primary facility will be shipped to secondary quarantine facilities, and all such material will be shipped under APHIS permits (see Section V.C.3), and will be accompanied with proper documentation forms (see Section V.D). The forms shall be clearly marked "For Quarantine Study Only." No field release of these organisms will be made without the clearance by APHIS and the Quarantine Officer and Research Leader of the primary facility from which the organisms were obtained, [FOLLOWING PHRASE RETAINED PENDING DECISIONS BY ARS AND APHIS.] or following review by the BCAC. [END OF PHRASE]

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY EITHER ARS AND APHIS, OR BOTH.]

B. Interagency Biological Control Advisory Committee (BCAC).

The BCAC is an interagency advisory group proposed to be established to provide technical support and advice to ARS and/or APHIS, upon request: (1) in evaluating risks with specific requests for permits to import or release exotic biological control agents; and (2) in establishing criteria for appropriate evaluation of requests for permits involving biological control organisms. The BCAC will not be involved in making regulatory decisions; it will be consulted regarding proposed importations and releases, primarily in regard to environmental safety factors, in cases in which Federal or State regulatory agencies seek further scientific input to make a regulatory decision, and can serve to resolve any substantive disagreements between APHIS and applicants, or upon specific appeal by biological control research workers, etc. See Attachment 8 for an outline of procedures involving BCAC for providing APHIS and/or ARS with such advice, and Section V.C below for specific information in regard to field release of introduced biological control agents. All communications with BCAC should be addressed to its Executive Secretary.

After final review of information concerning arthropod biological control agents assigned to Classes B and C (see Section V.A.2), including information resulting from tests conducted in primary or secondary quarantine facilities, if any doubt remains as to the propriety of release of the organism from quarantine status, the question may be placed before BCAC for an informal review. This may be done by the Quarantine Officer of the facility in which the tests were conducted, or by research workers at that or other facilities who are interested in obtaining clearance for such release.

Documentary evidence pro and con will be accumulated for presentation to BCAC, together with an explanatory memo stating the position of the involved Quarantine Facility, and supportive or contradictory memoranda from interested research and regulatory officials. BCAC will respond with a consensus opinion indicating support or lack of support for the proposed quarantine action. If the consensus opinion is favorable, the Quarantine Facility can proceed with field release or interstate procedures, in which the BCAC may be more formally involved (see Section V.C).

[END OF SECTION RETAINED PENDING ARS OR APHIS ACTION]

C. Field Release or Interstate Shipment of Foreign Arthropod Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests.

1. General Approval and Permit Requirements.

Specific approval procedures for field release or interstate shipment of foreign arthropod biological control agents for arthropod pests cleared for release from quarantine under procedures indicated in Section V.A above, will be stated in the QOP [FOLLOWING PHRASE RETAINED PENDING DECISIONS BY APHIS AND ARS.] and Compliance Agreements or Memoranda of Agreement between the involved Quarantine Facilities, APHIS, and State regulatory agencies. [END OF PHRASE]

In general, these approval procedures will include: a) A requirement for State approval and an APHIS permit for all initial interstate shipments containing specified host arthropod or plant material; b) A similar requirement for all initial shipments of foreign beneficial organisms "For Study in Quarantine Only" to secondary or other primary quarantine facilities; c) In certain cases, a requirement for specific approval from APHIS (PPQ or VS) for the initial field release of an exotic species in the United States; d) A requirement for an APHIS permit and State approval for all initial shipments or field releases of exotic species to/by ARS individuals or facilities in States having regulations requiring such permits or approval, or in States whose regulatory agencies have formally requested notification prior to such shipments or releases; e) Proper documentation of all shipments and field releases from quarantine including periodic notification of PPQ, VS (as appropriate), BCDC, and pertinent State agencies; and f) Adequate packaging to prevent escape of organisms during transit. The Quarantine Officer is responsible for adherence to these procedures.

All applications for State approvals or APHIS permits for field release or interstate shipment shall be initiated by use of PPQ Form 526 (see Attachment 1), [FOLLOWING PHRASES RETAINED PENDING DECISIONS BY ARS AND/OR APHIS.] if the biological control organism to be released or shipped is considered by APHIS to be a plant or veterinary pest, or live host/prey organisms are to be included in the release or shipment, or PPQ/ARS Form __ (see Attachment 2), if only biological control organisms not considered plant or veterinary pests are to be included in the shipment or release. [END OF RETAINED PHRASE - SEE ALSO NOTE IN SECTION III.A.1 ABOVE.]

2. Field Release by ARS Facilities.

a. Federal and State regulations.

Before a new candidate foreign biological control agent can be field released or shipped interstate from quarantine, provisions must be made to meet the requirements of certain Federal and State regulations impacting the introduction of exotic organisms for biological control of pests. The Federal regulations involved, in addition to the Plant Quarantine Act (PQA) and Federal Plant Pest Act (FPPA) already mentioned in these Guidelines as regulating the importation and movement of live organisms, include the following: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the National Environmental Policy Act (NEPA); the Endangered Species Act (ESA); and the Federal Food, Drug, and Cosmetic Act (FFDCA). The ARS Research Leader, Quarantine Officer, and involved researcher, are responsible for adherence to the requirements of regulations under these Acts as noted below.

FIFRA: Under this Act, which is administered by the Environmental Protection Agency (EPA), all biological agents used for control of pests are classified as pesticides, and thus their movement and use is regulated by EPA. However, EPA has exempted from regulation under FIFRA invertebrate biological control organisms on the grounds that they are adequately regulated by the USDA, primarily by APHIS under the PQA and FPPA and associated regulations.

NEPA: Under this Act, all Federal or Federally-supported agencies must consider the environmental impact of major actions that may significantly affect the quality of the human environment in the U.S. USDA agencies interpret this to mean that, with certain exceptions, an Environmental Assessment (EA) is required for the initial field release of exotic biological control agents in the U.S. That is, an environmental risk analysis must be applied in such actions by ARS (ARS, 1986), and for the issuance of Federal permits by APHIS for the initial field release of introduced plant pests or potential plant pests. [THE FOLLOWING SECTIONS ARE RETAINED PENDING DECISIONS AND ACTIONS BY ARS AND APHIS.] A proposed list of beneficial arthropod groups that offer little or no risk of having significant adverse effects on the quality of the environment, and thus are proposed to be exempt from the requirement of an EA, has been prepared by ARS and other biological control scientists (see Attachment 9). The proposed criteria for excluding these groups of organisms from the EA requirement prior to issuance of an APHIS permit are listed on Attachment 10. The list of exempted organisms may be amended by application to the ARS and/or APHIS Administrators. APHIS may issue permits for the initial release of species of the groups of organisms represented on the list without a formal EA, but may require applicants to submit additional information in lieu of an EA to resolve questions about a proposed release of a biological control agent.

For initial release of organisms *not* exempted from a formal EA requirement, environmental assessment protocols have been prepared, the complexity of which vary with the level of risk involved. Attachments 11 and 12 present formats or protocols for providing information required for developing an EA required prior to issuance of a permit for initial release of non-exempted organisms. Attachment 13 provides the criteria used to determine the appropriate protocol to be used. In cases where the level of risk is high, an Environmental Impact Statement (EIS) would be required. However, for most non-exempted arthropod biological control agents for arthropod pests, the abbreviated format (Attachment 11) may generally be used. Either APHIS or ARS scientists or other officials will prepare the environmental documents required to obtain an APHIS permit for initial release. See Section V.B above for the role of the BCAC in the approval procedures. [END OF RETAINED SECTIONS]

ESA: This Act, administered by the Fish and Wildlife Service (FWS) of the USDI, concerns the impact of Federal actions on native endangered and threatened animals (including arthropods) and plants in the U.S. Some of the safety evaluations noted in Sections II.B and V.A.3 and below are designed to meet these concerns. Comments on these concerns and results of any test results related to them should be noted on the permit application or EA protocol document.

FFDCA: This Act, administered by the Food and Drug Administration (FDA), concerns the adulteration of food products by "filthy" substances, including insects or insect-related components. This Act impacted on the use of arthropod natural enemies to control pests in stored food products; these are considered pesticides and are subject to the requirements for tolerances under FFDCA. However, as noted above, these kinds of pesticides have been exempted from registration requirements under FIFRA. The EPA, with the concurrence of the FDA and USDA, has now **proposed to have** exempted from the requirement of a tolerance the natural enemies used in control of pests of stored products listed in Attachment 14 (EPA, 1991). When applying for a permit for the initial release of any arthropod natural enemy for use in stored products not so exempted from requirement of a tolerance, an evaluation of its potential as an adulterant of foodstuffs must be made, as indicated in Section II.B.1.c.2) of these Guidelines, and comments on this evaluation should be made on the permit application or EA protocol document.

Several States have laws and regulations regarding environmental policy and/or endangered species within their boundaries, similar to NEPA and ESA. In addition, certain States have regulations requiring permits or approval prior to shipment or release of arthropod biological control agents within their borders, or have otherwise formally requested notification prior to such importations or releases (see Attachment 15). Knowledge of and adherence to pertinent State regulations are responsibilities of the involved ARS Quarantine Facility researcher, Research Leader, and Quarantine Officer, prior to the initial release of biological control organisms in the U.S.

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY EITHER ARS AND APHIS, OR BOTH.]

b. Initial releases of arthropod biological control agents of arthropod pests in the United States.

Prior to initial field releases of newly-imported biological control agents for arthropod pests in the United States, appropriate State approval(s) and a USDA permit must be obtained by the ARS Quarantine Facility or other facility proposing to make the initial release. All applications for State approvals or USDA permits for field release or interstate shipment shall be initiated by use of PPQ Form 526 (see Attachment 1), if the biological control organism to be released or shipped is considered by APHIS to be a plant or veterinary pest, or live host/prey organisms are to be included in the release or shipment, or by use of PPQ/ARS Form __ (see Attachment 2), if only biological control organisms not considered plant or veterinary pests are to be included in the shipment or release. SEE NOTE IN SECTION III.A.1 ABOVE.

Section A of the forms will be completed indicating the intent to field release the biological control agent, and the form will be sent to the State regulatory agency (see Attachment 4) in which the release is proposed, along with an appropriate environmental document if required (see comments below, and NEPA requirements above). If an EA is deemed not to be required, it must be documented on the permit application that criteria for exclusion of the organism from the EA requirement have been met (see Attachment 10). State approval will be indicated in Section B of the form, and the form will be forwarded by the State official to APHIS for completion of Section C indicating approval or disapproval of the release.

If an EA is required, there are two possible scenarios:

(1) An appropriate EA protocol document (see NEPA requirements above and Attachments 11-13) will be prepared by the permit applicant and included with the appropriate permit application form when submitted to the State regulatory official in which the initial field release is intended. State approval will be indicated in Section B of the form, and the form will be forwarded by the State official to APHIS, where the document will receive an in-house review in APHIS, and/or by BCAC as may be requested. After a favorable review, APHIS will prepare an EA and, if this results in a Finding of No Significant Impact (FONSI), APHIS-PPQ will complete Section C of the permit application form. PPQ will return the completed form (the permit) to the applicant, with copies to the involved Quarantine Facility (if this differs from that of the applicant), and to the BCDC and the pertinent State regulatory agency. The permits, valid for 5 years, may be renewed for another 5-year period, after which no further permits for release of the permitted organism in that State shall be required. The Quarantine Officer shall be responsible for permit renewals.

(2) For the second option, the ARS researcher proposing the initial U.S. field release of an introduced biological control agent will submit the appropriate EA protocol documents (see Attachments 11-13) to the pertinent ARS office for review. A FONSI will subsequently be prepared by ARS which will be then be included with the permit application form when sent to APHIS via the appropriate State regulatory agency. APHIS-PPQ may then issue the permit and send copies as in option 1.

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For certain initial releases in the State in which the ARS Quarantine Facility is located of organisms exempted from the requirement of an EA, APHIS and/or State approval *may* be obtained on the same permit application form used for requesting importation permits (see Section III.A), by indicating the intent to release on the form when first submitted. In certain cases, State regulatory officials, in consultation with the Quarantine Facility and APHIS, may elect to issue "blanket authorizations" for releases of specified arthropod biological control agents; such a provision is to be reflected in the facility's Compliance Agreement. In other cases, telephone approvals may be obtained as required in emergency situations; these should be documented in writing as soon as possible. In other cases, ARS, State, or APHIS officials may elect to request an opinion on proposed releases from an *ad hoc* panel of knowledgeable biological control scientists or the BCAC (see Section V.B).

[END OF RETAINED SECTION REQUIRING DECISIONS BY ARS AND/OR APHIS]

- c. Subsequent releases of arthropod biological control agents for arthropod pests.

Completion by the Quarantine Facility or other ARS shipping/releasing facilities of Section A of the appropriate permit application form for State regulatory agencies is also required for subsequent releases of the same organism in additional States, if those States require permits or prior approval for such releases (see Attachment 15). Unless the State requires or requests an APHIS permit (completion of Section C of the form) or such permit is otherwise required, the form may then be returned to the shipping/releasing facility by the State regulatory agency. The Quarantine Officer or pertinent personnel at other facilities will maintain a file of such State approvals, and will supply copies to APHIS and BCDC. If an APHIS permit is required or requested by the State, the permit application form will be forwarded by the State official to APHIS. Based upon prior release approval and State recommendation, APHIS will complete Section C and distribute copies of the completed form (the permit) as above.

After permits are obtained for their initial releases, no other prior action is required for subsequent field release of hand-carried foreign arthropod biological control agents in States not so requiring or requesting such action. However, appropriate regulatory agencies in these and all other States in which releases are made shall routinely be informed periodically in writing of all releases made within their boundaries by ARS facilities making those releases. APHIS and BCDC shall also be similarly informed. The ARS Quarantine Officer or Research Leaders at other ARS facilities releasing introduced biological control agents shall be responsible for such notification.

3. Interstate Shipment from Quarantine and by Non-Quarantine Facilities/Personnel Engaged in Receipt or Culture of Foreign Arthropod Biological Control Agents for Arthropod Pests.

The intended recipient of foreign arthropod biological control agents for arthropod pests to be shipped through or otherwise received from ARS quarantine facilities, or from ARS non-quarantine facilities, shall be responsible for obtaining State approvals and APHIS permits for such interstate shipments, if such approvals and/or permits are required or requested by regulatory officials of the pertinent State. Such State approvals and/or APHIS permits will be obtained using the appropriate permit application form in the same manner as such approvals or permits for field release are obtained as discussed above (see Section V.C.2). The Quarantine Officer can assist the intended recipient in completion of Section A of the form, as may be required.

If the material is to be field released by the recipient, this intent must be clearly indicated on the permit application form. In cases of initial U.S. releases, State or APHIS officials may elect to request an opinion from an *ad hoc* panel of knowledgeable biological control scientists or the BCAC as described above; see procedures outlined above.

If a PPQ permit is required, the form will be forwarded to APHIS by the State regulatory agency for issuance of a permit (completion of Section C of the form) and APHIS will provide copies of the permit to the applicant, the involved Quarantine Facility or non-quarantine facility, BCDC, and the State regulatory agency. If no APHIS permit is required or requested, the State regulatory agency or intended recipient of the biological control material will forward the permit application form, with Sections A and B completed, to the quarantine or other facility and the shipment(s) may then be made. The Quarantine Officer or pertinent non-quarantine personnel will maintain a file of such permits and State approvals, and will provide copies of the latter to APHIS and BCDC.

Arrangements for State approvals and/or APHIS permits must be made well in advance of intended shipments, to prevent the loss of valuable live materials while awaiting approval procedures.

All foreign arthropod biological control agents shipped from ARS quarantine facilities will: a) be packaged in containers designed to prevent escape of the organisms during transport (see Section III.B); b) have a PPQ shipping permit label authorizing interstate shipment affixed to the outside of the package; and c) be accompanied by shipping record forms (see Section V.D).

ARS quarantine or non-quarantine culturing facilities may obtain a supply of APHIS interstate shipping labels from APHIS for use for shipments of pure cultures of arthropod biological control agents, if approval for their initial U.S. release has been obtained, a) to States not requiring individual approvals for such shipments, or b) to other States upon receipt of a State-approved permit application form for States not requiring an APHIS permit. These shipping labels will not be used for the rare cases in which live host materials (arthropod pests) or plant material are to be included in the shipments, or for shipments sent to secondary or other primary quarantine facilities "For Quarantine Study Only" (see Section V.A). In these cases, specific APHIS-issued permits and permit labels are required. [FOLLOWING SENTENCE IS RETAINED PENDING DECISIONS BY APHIS AND/OR ARS] No interstate shipments will be made by ARS Quarantine Facilities except under the conditions stipulated in the facility's Compliance Agreements. [END OF SENTENCE]

No prior action is required for interstate shipment of pure cultures of foreign arthropod biological control agents after their initial U.S. release to States not so requiring or requesting such action. However, appropriate regulatory agencies in these and all other States to which such shipments have been made will routinely be informed periodically in writing of the recipients and contents of all shipments made to their States by ARS quarantine and pertinent non-quarantine facilities. APHIS and BCDC shall be similarly informed. The ARS Quarantine Officer(s) or pertinent ARS Research Leaders shall be responsible for such notification.

D. Documentation of Quarantine Consignments, and Quarantine and Non-Quarantine Shipments and/or Field Releases of Introduced Arthropod Biological Control Agents for Arthropod Pests.

Because classical biological control projects involve the introduction, release, and establishment of organisms from other countries, it is important that importations and releases be properly documented, so that pertinent information on the origin and release of the imported organisms can be made available to other biological control researchers, ecologists, taxonomists, or Federal and State regulatory officials. Sometimes, imported natural enemies are not found to be established in the U.S. until a number of years have passed following the release(s), so records must be maintained on a long-term basis.

All consignments, shipments, and releases of material directly from quarantine made by ARS quarantine facilities will be documented by completion of AD Form 942 (Attachment 16), in accordance with instructions on the form. Section I of the form is to be completed by the Quarantine Officer, Section II, and Section III if appropriate, by the recipient of the material.

Material cleared for release from quarantine in accordance with procedures outlined in Section V.A above may be consigned to non-quarantine status for further study, culture, or field release by quarantine or non-quarantine personnel of the Quarantine Facility or of other facilities. In cases in which several consignments of material from the same incoming shipment or quarantine culture, a single AD Form 942 may be used to record the consignments, noting a range of consignment, receipt, and/or release dates in Sections I-III of the form. Further shipments or releases from non-quarantine cultures established from these quarantine consignments will be documented by use of the AD Form 943; see below.

Each shipment of material directly from quarantine made from ARS quarantine facilities shall be accompanied by an AD Form 942, with Section I completed. This form provides source, culture, and other information for the recipient of the shipment, and feedback information for the shipper on the results of the shipment. The recipient of the shipment must complete Sections II and III as applicable, and return the specified number of copies to the Quarantine Facility.

In cases where the foreign arthropod biological control agents shipped are not all immediately field released, but instead some or all are laboratory cultured for later field release, the ARS person or facility culturing the foreign species is responsible for documentation of all subsequent releases or shipments of that species until the culture is lost or discontinued. In cases in which interstate shipments are made of this cultured material (see Section V.C.3 above), documentation of those shipments by the culturing facility is also required. The AD Form 943 (Attachment 17) is available for use to provide recipients of shipments with source and culture information and shippers with feedback information from the recipients and for documentation of non-quarantine shipments and releases. However, this form need not be used, if a similarly detailed system of providing information and documenting shipments and releases of exotic arthropod biological control agents is used and pertinent reports are made available to BCDC.

All ARS quarantine facilities, and the BCDC, will be provided with supplies of AD Forms 942 and 943, and will provide, upon request, supplies of the latter form to persons and facilities engaged in non-quarantine culture, shipment, release, and recolonization activities.

The Quarantine Officer of each ARS Quarantine Facility, primary or secondary, shall be responsible for assuring proper documentation of consignments, shipments, and/or releases of foreign arthropod biological control agents, using AD Forms 942 and 943 as appropriate, and for distribution of the copies of the forms, in accordance with instructions on the forms.

Periodic reports of quarantine and non-quarantine shipment and release activities may be required of the pertinent facilities by BCDC, PPQ and/or State regulatory agencies.

Because of the possibility that recoveries of natural enemies may not materialize until several years after releases have been made, it is suggested that a computerized data base similar to that proposed by Dysart (1981) be used by ARS quarantine facilities to permit rapid searches for information on organisms that have been received in quarantine. This is most certainly a necessity for quarantine facilities with a high volume of shipments, 50 or more per year. Copies of all importation, consignment, and release forms (AD Forms 941 and 942) should be provided by the quarantine facility to the BCDC so that the data can be entered into the national Releases of Beneficial Organisms in the United States and Territories (ROBO) database (see Knutson et al., 1987, and Coulson et al., 1988).

E. Voucher Specimens.

Retention of specimens representing imported and released material is required in some cases, and is highly recommended in all cases, in order that vouchers relating to the importation and release of exotic organisms in the United States will be available for immediate or future study by taxonomists and biological control researchers. Voucher specimens are needed particularly to document field release of exotic organisms and to permit *ex post facto* comparisons with U.S. field recovered material to facilitate verification of establishments.

Of particular importance are voucher specimens to document:

- 1) The initial field release in the United States of a foreign arthropod biological control agent by quarantine or other facilities; these voucher specimens should include specimens from each major geographical area (at least from each country) of origin of the released material.

2) Subsequent field releases of the same species from new major geographical areas.

3) Field releases from long-established laboratory cultures; such cultures should be periodically sampled and specimens vouchered to verify that cultures have retained their integrity.

ARS Quarantine Officers are responsible for obtaining representative specimens documenting the various actions noted above, and for their proper preparation and labeling, and for their curation at the Quarantine Facility.

[THE FOLLOWING SECTIONS ARE RETAINED PENDING DECISIONS BY ARS.]

As noted in Attachment 18, the Quarantine Officer shall send certain properly prepared specimens to BCDC for inclusion in the proposed national voucher collection. The Quarantine Officer shall send with the specimens information on the origin and field release of the material represented by those specimens, and on their taxonomic identity and the name of the person making this determination; this information can be provided in the form of a reference to the file number of the pertinent shipment record form (AD-942 or -943) recording the release (see Section V.D).

BCDC will be responsible for providing the specimens with distinctive Voucher Specimen labels, with the information as noted above, and will send some of the specimens for deposit in the National Collection of Insects of the U.S. National Museum of Natural History, Washington, DC; others will be sent for deposit in the Canadian National Collection, Ottawa, Ontario, on a reciprocal basis. The remaining Voucher Specimens will be retained by BCDC for inclusion in the proposed U.S. National Voucher Collection for Introduced Beneficial Arthropods (see Attachment 18). See Steyskal et al. (1986) for information on preparation of arthropod specimens.

Additional voucher material representing newly imported or newly cultured material may be required from time to time. It is recommended that all quarantine facilities and facilities engaged in culture activities retain properly prepared and labeled specimens documenting all importations, releases, cultures, or recoveries, as described in Attachment 18, for reference purposes. [END OF RETAINED SECTION]

VI. Interstate Shipment of Native or Naturalized Arthropod Biological Control Agents for Arthropod Pests.

All ARS facilities and personnel engaged in the field-collection, recolonization, or laboratory culture of native or naturalized arthropod biological control agents for shipment to other States or U.S. Territories shall be responsible for ascertaining and adherence to quarantine and other requirements of the States or Territories to which the material is to be sent (see Attachments 4 and 15). State or Territorial approvals or APHIS permits are required for such shipments only if so stipulated by State or Territorial requirements. These approvals or permits shall be obtained by the intended recipients in the same manner as indicated in Section V.C.3 of these Guidelines. No APHIS shipping labels are required, except as required by pertinent State or Territorial regulations.

All ARS facilities engaged in recolonization of established foreign (i.e., "naturalized") arthropod biological control agents for arthropod pests, or interstate shipment of laboratory cultured or field-collected native or naturalized species, will maintain a record of such recolonizations or shipments, including records of origin, dates and sites of recolonization, dates of shipment, and shipment recipients, and will provide such records to BCDC and APHIS on an annual basis. State or Territorial regulatory agencies may also request annual notification of shipments made to facilities or personnel within their boundaries. The AD Form 943 (Attachment 17) is available for use by ARS facilities for providing information to the recipient and obtaining feedback information, and for documenting the recolonizations, shipments, and/or releases. However, this form need not be used, if a similarly detailed system of providing information and documenting shipments and recolonizations of exotic arthropod biological control agents is used and pertinent reports are made available to BCDC and others as may be required.

Although no voucher specimens are required, it is recommended that all facilities engaged in recolonizations or interstate shipment of native or naturalized arthropod biological control agents maintain voucher specimens to document the recolonizations and shipments for possible future reference.

VII. Export of Arthropod Biological Control Agents for Arthropod Pests to Other Countries.

All ARS domestic and overseas facilities and personnel making shipments of arthropod biological control agents to foreign countries will determine whether or not quarantine regulations exist in the country to which the shipments are to be made, including any requirement for quarantine entry permits, and are responsible for adherence to those regulations, if any.

All shipments to foreign countries shall be shipped in containers designed to prevent escape of organisms. Host materials (arthropod or plant) will not be included in the shipments unless absolutely required, and unless specific approval for such inclusion is obtained from the foreign government.

[STATEMENT RETAINED PENDING DECISIONS BY ARS AND APHIS.] Although not legally required, it is recommended that an APHIS shipping label be affixed to the outside of the package near the address labels, together with the foreign permit label, if applicable. These shipping permit labels may be obtained from ARS-BCDC, who will issue the labels only after receipt of documentary evidence that all foreign quarantine regulations have been met or that there are no quarantine regulations (e.g., photocopies of permits or relevant correspondence). [END OF STATEMENT]

As a courtesy and for the information of the foreign recipient, shipment record forms (AD Form 941)(Attachment 6), with Section I completed, should accompany each shipment, with a request that Section II of the form be completed, and the form returned to the sender. The sender is responsible for distribution of copies of the form in accordance with instructions on the form.

Although no voucher specimens are required, it is highly recommended that the sender of shipments to foreign countries retain such specimens to document the contents of the shipments for possible future reference.

VIII. Recommended References.

- Agricultural Research Service. 1986. Final regulations for implementing National Environmental Policy Act (NEPA). *Federal Register* 51(186): 34190-34192.
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PPQ Form 526: Application and Permit to Move Live Plant Pests or Noxious Weeds

SEE NO. 1 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed PPQ/ARS Form __: Application and Permit to Move Living Beneficial Organisms

SEE NO. 2 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

List of ARS Biological Control Quarantine Facilities Proposed to be Approved for Receipt of Foreign Arthropod Parasites and Predators of Arthropod Plant Pests and for Foreign Biological Control Agents for Arthropod Medical and Veterinary Pests

TO BE PREPARED

List of Plant Regulatory Officials of U.S. States and Territories, Canada, and Mexico

SEE NO. 3 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

VS Form 16-3: Application for Permit to Import or Transport Organisms or Vectors

SEE NO. 4 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

AD Form 941: Biological Shipment Record - Foreign/Overseas Source

SEE NO. 5 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Form ARS-748: Identification Request

SEE NO. 6 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Structure and Procedures of the Proposed Biological Control Advisory Committee (BCAC)

SEE NO. 7 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed List of Invertebrate Biological Control Agents Exempted from the Requirement of a Formal Environmental Assessment

SEE NO. 8 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Criteria for Exemption of Invertebrate Biological Control Agents for Arthropods from the Requirement of a Formal Environmental Assessment for Field Release

SEE NO. 9 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Abbreviated Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Exotic Invertebrate Biological Control Agents of Arthropod Pests: Short Format

SEE NO. 10 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Biological Control Agents: Long Format

SEE NO. 11 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Criteria for Biological Control Agents Requiring Either (1) an Abbreviated or (2) a Detailed Protocol Document for Providing Environmental Assessment Information

SEE NO. 12 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

**Proposed List of Arthropod Parasites and Predators Exempted
from the Requirement of a Tolerance for Residues in Stored Food Products
in Warehouse or Related Situations
(See 40 CFR part 180.xxx)**

The following parasitic/parasitoid and predatory arthropods are exempted from the requirement under FIFRA of a tolerance for residues when they are used in accordance with good agricultural and pest control practices in warehouse and other bulk storage situations to control arthropod pests in or on bulk or bagged, stored, raw, whole grains such as corn, small grains, rice, soybeans, peanuts and other legumes, and related warehouse-stored commodities, such as meal or flour:

Phylum Arthropoda

Class Insecta

Order Hymenoptera

Family Trichogrammatidae (species of the genus *Trichogramma*)

Family Braconidae (species of the genus *Bracon*)

Family Ichneumonidae (species of the genera *Venturia* and *Mesostenus*)

Family Pteromalidae (species of the genera *Anisopteromalus*, *Choetospila*, *Lariophagus*, *Dibrachys*, *Habrocytus*, and *Pteromalus*)

Family Bethyridae (species of the genera *Cephalonomia*, *Holepyris*, and *Laelius*)

Order Heteroptera

Family Anthocoridae (species of the genera *Xylocoris*, *Lyctocoris*, and *Dufouriellus*)

(Proposed rule published by EPA in Federal Register 56 (2): 234-235, 1/3/91)

List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries

SEE NO. 13 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES
TO BE PREPARED

AD Form 942: Biological Shipment Record - Quarantine Facility

SEE NO. 14 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

AD Form 943: Biological Shipment Record - Non-Quarantine

SEE NO. 15 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Structure and Procedures of the U.S. National Voucher Collection for Introduced Beneficial Arthropods

SEE NO. 16 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

**Proposed ARS Guidelines for
the Importation, Interstate Movement, and Field Release in the United States
of Foreign Arthropod-Parasitic Nematodes for Biological Control of
Arthropod Pests of Plants, Humans, and Domestic Animals,
and Vectors of Plant, Human, and Animal Pathogens,
and for the Interstate Movement and Export of Foreign and Native Nematodes
for Research on Biological Control of Such Pests¹**

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Attachments

1. PPQ Form 526: Application and Permit to Move Live Plant Pests or Noxious Weeds
2. **Proposed** PPQ Form __: Application and Permit to Move Living Beneficial Organisms
3. List of ARS Biological Control Facilities **Proposed to be** Approved for Initial Receipt of Foreign Nematode Biological Control Agents for Arthropod Pests
4. List of Plant Regulatory Officials of U.S. States and Territories
5. VS Form 16-3: Application for Permit to Import or Transport Organisms or Vectors
6. AD Form 941: Biological Shipment Record - Foreign/Overseas Source
7. List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries
8. **Proposed** List of Invertebrate Biological Control Agents Exempted from the Requirement of a Formal Environmental Assessment
9. **Proposed** Criteria for Exemption of Invertebrate Biological Control Agents for Arthropods from the Requirement of a Formal Environmental Assessment for Field Release
10. **Proposed** Abbreviated Protocol Document for Providing Data for Preparation of Environmental Assessments for Initial Field Release of Exotic Invertebrate Biological Control Agents: Short Format
11. **Proposed** Detailed Protocol Document for Providing Data for Preparation of Environmental Assessments for Initial Field Release of Exotic Invertebrate Biological Control Agents: Long Format
12. **Proposed** Criteria for Biological Control Agents Requiring Only an Abbreviated Protocol Document for Providing Environmental Assessment Information (Short Format)
13. Structure and Procedures of the **Proposed** Biological Control Advisory Committee (BCAC)
14. AD Form 942: Biological Shipment Record - Quarantine Facility
15. AD Form 943: Biological Shipment Record - Non-Quarantine

¹ Original draft prepared by J. R. Coulson from 1978 draft material by A. M. Heimpel and W. R. Nickle (ARS); revisions by J. R. Coulson from comments received from W. R. Nickle from a review by several U.S. nematologists in 1990, and following review by Working Session participants (see Appendix 1) in January, 1991; further comments incorporated from later review by G. C. Smart (University of Florida).

I. Intent and Scope of these Guidelines.

These Guidelines are intended to provide detailed procedures required for the importation and interstate shipment of foreign arthropod-parasitic nematodes for diagnosis and laboratory research, and for biological control research and development programs involving field release of the foreign nematodes in the United States. These procedures are designed to insure that every reasonable precaution will be taken to contain and prevent the escape or release of organisms that are injurious to agricultural, horticultural or forestry commodities, humans and domestic animals, or other beneficial organisms, or that are otherwise detrimental to the environment.

Organisms for which these Guidelines are intended include all arthropod-parasitic species of the nematode families Mermithidae, Sphaerulariidae, Steinernematidae, Heterorhabditidae, Aphelenchidae, and other species of the Phylum Nemata that are to be studied or utilized as parasites in the biological suppression of arthropod pests, and for imported host materials infected with these organisms. Separate Guidelines exist for the importation and release of arthropod parasites and predators of arthropods, invertebrates (including nematodes) for control of weeds, and invertebrates (including nematodes) and microbial pathogens for control of plant nematodes.

These Guidelines also include procedures for the interstate movement of foreign arthropod-parasitic nematodes and for the export of foreign or domestic nematodes to other countries for research on biological control of arthropod pests.

Some organizational abbreviations used in these Guidelines are:

APHIS - Animal and Plant Health Inspection Service, USDA
ARS - Agricultural Research Service, USDA
BCAC - Interagency Biological Control Advisory Committee Proposed
BCDC - Biological Control Documentation Center, ARS
EPA - Environmental Protection Agency
FDA - Food and Drug Administration
FWS - Fish and Wildlife Service, USDI
NL - Nematology Laboratory, ARS
NPS - National Program Staff, ARS
PHS - Public Health Service, USDHHS
PPQ - Plant Protection and Quarantine, APHIS
SEL - Systematic Entomology Laboratory, ARS
USDA - United States Department of Agriculture
USDHHS - United States Department of Health and Human Services
VS - Veterinary Services, APHIS

II. Summary of Procedural Policies and General Safety Considerations.

A. Summary of Procedures for Importation, Interstate Shipment, Field Release, and Export of Nematode Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests.

The Plant Quarantine Act of 1912 and the Federal Plant Pest Act of 1957 prohibit the importation and movement of plant and animal pests, pathogens, vectors, and articles that might harbor these organisms, unless authorized by the U.S. Department of Agriculture (USDA). The National Environmental Policy Act of 1969 (NEPA) contains provisions that impact upon the release of exotic organisms into the environment. Regulations under these Acts are enforced by the Plant Protection and Quarantine Programs (PPQ) and Veterinary Services (VS) of the Animal and Plant Health Inspection Service of the USDA. The importation and shipment of pathogens and vectors of pathogens of humans are regulated by the Public Health Service (PHS), USDHHS; if such importations or movements are contemplated by ARS facilities, information on these regulations can be obtained from the Foreign Quarantine Program, Centers for Disease Control, PHS, USDHHS, Atlanta, GA 30333, or PHS Quarantine Stations at U.S. ports of entry.

The determination of the adequacy of containment facilities for receipt and laboratory testing of foreign organisms, and of the technical competence of investigators, is the responsibility of APHIS (PPQ and VS), and pertinent State Departments of Agriculture, (and PHS in the case of importation of vectors of human pathogens). Determining the requirements that must be met for introduction of such organisms into quarantine or into the field is also their responsibility. [NOTE: THE FOLLOWING STATEMENT CONTAINS A PROPOSAL AND IS RETAINED PENDING ACTION BY ARS, APHIS, AND OTHER AGENCIES.] In the case of foreign beneficial organisms for biological control, an interagency Biological Control Advisory Committee (BCAC) has been [proposed to be] established to provide advice to APHIS (and the PHS as may be required) and researchers, upon request, on proposed importations and releases of foreign biological control agents in the United States. APHIS, PHS, and BCAC are concerned that safety considerations such as those listed below are made prior to importation or field release of foreign biological control organisms in the United States. [CLOSE OF STATEMENT]

Certain of the below listed safety considerations may be made during the overseas exploration phases of a biological control introduction program, i.e., before importation of the proposed biological control agent, while others can be made during the domestic phases of the introduction program. The procedures detailed in these Guidelines are designed to assure that such considerations are made and necessary precautions are taken.

It is highly recommended that the following references be studied in conjunction with these Guidelines: Poinar (1979); Lima (1983); Coulson and Soper (1989); Nickle et al. (1988); Way (1990); Nguyen and Smart (1991); Georgis et al. (1991); and Howarth (1991).

The more important conditions required for the importation and release of foreign beneficial nematodes for control of arthropod pests as reflected in these Guidelines can be summarized as follows:

- 1) All foreign organisms shipped to the United States or later shipped interstate must be shipped in containers meeting USDA standards, and must be shipped with APHIS (and as necessary PHS) approval. See Sections III, V.B, and VI.
- 2) Foreign nematodes for biological control, with few exceptions, must be received, with proper documentation, in facilities approved by APHIS (and PHS as necessary), where at least preliminary

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examination will be made and all contaminants, exotic host material, soil, and other materials deemed to be of potential hazard or detriment are to be destroyed, and where the foreign material will be tested or all or portions re-routed for testing to other competent investigators at approved laboratories will be made, as may be deemed necessary or desirable. An appropriately trained Containment Officer will be duly appointed who will be responsible for all receipt and containment operations. See Sections III and IV.

3) Appropriate taxonomic level identifications of the foreign nematodes are required prior to their release or consignment from containment. See Section V.

4) Evaluation of the potential impact of the proposed field release on nontarget organisms, and other safety considerations as listed below must be made prior to field release of the organism. An Environmental Assessment may be required prior to field release of the nematode. See Sections II.B and V.

5) Where possible, it is recommended that other potential hosts of the nematode (particularly beneficial arthropods) in the original foreign collection area be examined to determine whether any of these may be attacked by the nematode species to be imported. Determination of "native" nematode parasites of the target arthropod or close relatives present in the proposed field release site is also recommended. See Sections III and V.

6) Voucher specimens to document the field release of exotic nematodes are required, and certain other documentary procedures are to be followed, during which APHIS and other officials are to be kept informed of all releases and shipments. See Sections III.C, IV.C, and V.E-F.

7) For interstate shipment and export of beneficial nematodes, adherence to quarantine requirements of the pertinent States and Territories of the United States and foreign countries is necessary prior to the shipment of the beneficial nematodes into those States, Territories, or countries. See Sections VI and VII.

B. Safety Considerations Required for Importation and Field Release of Foreign Nematode Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests in the United States.

The following safety considerations, discussed further throughout these Guidelines, must be evaluated prior to considering the importation or release of foreign nematodes for biological control of arthropods into the United States:

1. Importation.

a. Parasitized phytophagous arthropods.

The introduction of host material should be restricted as much as possible to shipping dead parasitized hosts. If it is necessary to ship live arthropods, they must be destroyed in containment as soon as possible. All shipments containing live arthropod host material should be sent initially to an approved arthropod quarantine facility, where all plant, soil, and live arthropod material will be destroyed, prior to shipment of the nematode material to the approved nematode receiving facility.

b. Parasitized biting insects, ticks, and mites - Vectors of vertebrate disease.

Parasitized living and dead vectors of vertebrate disease must be received in a specially approved arthropod quarantine facility, and live arthropod material must be destroyed there as soon as possible.

c. Live nematodes.

Entomophagous nematodes are obligate insect parasites and are specialized to the point that their mouth parts are adapted to their role of parasitizing arthropods, thus making it impossible for them to feed on plants. Therefore, shipments of live arthropod-parasitic nematodes from foreign sources, without host material, may be received at certain APHIS-approved containment facilities. Provisions must be made, either prior to shipment or at the containment facility, for careful examination of the specimens to insure that only arthropod-parasitic nematodes are included in the shipment.

Entomophagous nematodes should be treated in four groups.

(1) Mermithidae: The highly specialized, arthropod-feeding nematodes of this family may be introduced after identification to family level in specified ARS facilities. Adults, post-parasitic juveniles, or eggs, separated from the host arthropods, should be placed in sterilized soil or sand in an approved container for shipment to approved nematode containment facilities for identification, and for study or transshipment.

(2) Sphaerularidae: Infective stages of nematode parasites identified to this family, in sterile soil or sand, and separated from the host arthropod, can be shipped to a specified ARS facility for identification, and for study or transshipment. As noted above, should infested host arthropods be necessary to insure that this type of nematode survives, the shipments should be sent to an approved arthropod quarantine facility where the nematodes can be retrieved from the hosts. Identifications of the host arthropods should be confirmed by competent arthropod taxonomists.

(3) Steinernematidae and Heterorhabditidae: Dauer, or resting stage, juveniles of these nematodes should be shipped in sterile sand or soil or on artificial media such as described by Dutky (1974). Containers should be opened in a Class I or higher Biological Containment Chamber in order to isolate, culture and identify the associated bacteria, when the bacterial associates may be other than species of the genus *Xenorhabdus*. After this initial safety consideration is made, these nematodes can be forwarded to competent, qualified investigators. Heterorhabditid and steinernematid nematodes and their associated bacteria should be investigated either at the selected receiving facility or by a qualified investigator selected by the receiving facility and approved by APHIS. No field releases should be contemplated without this thorough investigation and only after the nematode and any bacterial associates have been identified.

(4) Aphelenchoidea and other nematode groups: Nematodes of groups whose biologies are generally less well known than the above noted groups may be treated in the same manner as sphaerulariid or steinernematid nematodes. However, special attention to biological studies is needed under containment, and, if not already known for the family of the nematode being imported, the presence or absence of microbial associates of the imported nematode should be determined before its consignment from domestic containment facilities.

2. Field Release.

Submittal to USDA and State authorities of an Environmental Assessment (EA) may be required to receive a USDA permit for the field testing of foreign nematodes for biological control. In general, the environmental considerations to be documented in the EA, if required, or otherwise to be documented, include:

- a. Protection against release of nematodes affecting plants or vertebrates.
- b. Protection against release of nematodes inimical to native or introduced beneficial arthropods, including biological control agents for arthropods and weeds, pollinators, and endangered arthropod species.

III. Initial Importation of Foreign Nematodes for Biological Control of Arthropod Pests.

Research workers should obtain as much pertinent information as practical concerning foreign biological control agents proposed for importation prior to their shipment to the United States. This should include as much information as practical on the identification of the nematode and its host(s)/prey, and pertinent biological information based on literature reviews and field observations, to assess the potential usefulness and safety of the candidate biological control agent. Also, as indicated above, if possible, special emphasis should be given to noting other potential hosts of the nematode (particularly beneficial arthropods) in the original foreign collection area to determine whether any of these may be attacked by the same nematode species being imported; this information can be useful in studies to determine the potential host range of the imported species.

Precautions as indicated in this Section of these Guidelines are designed to provide for the safe shipment and receipt of all foreign nematode biological control agents for arthropod pests of plants, man, and domestic animals, regardless of the amount of preliminary information obtained overseas. Additional information may be required to be accumulated overseas prior to clearance of the biological control agent for release from quarantine.

In connection with overseas studies and explorations, it is recommended that the following references be consulted: Nickle et al., 1988, and Nguyen and Smart, 1991.

All potential biological control agents for arthropod pests shipped to the United States from foreign sources must: 1) have appropriate APHIS shipping permit labels affixed to the outside of the packages; 2) be shipped in containers meeting certain specifications; 3) be accompanied by specified documentation; and 4) be routed to and received and opened in designated APHIS-approved facilities (see also Section IV), with certain exceptions.

Inclusion of plant or host arthropod material, or soil, in shipments from foreign sources will be limited to those cases in which such inclusion is a necessity. Should potentially useful organisms and/or host material not covered by APHIS permits or authority be received in quarantine, APHIS should be notified immediately and positive identification made for post-shipment approval.

A. Approvals, Permits, and Shipment Labels for Importation.

1. General Procedures.

APHIS permits and permit labels are required for importation of pure cultures of beneficial organisms and of parasitized host material or soil from foreign sources for diagnostic purposes or laboratory research. In certain cases, PHS permits may also be required.

a. For nematodes for control of arthropod plant pests.

An APHIS permit and shipment labels for individual shipments or series of shipments of nematode parasites of arthropod plant pests from foreign areas shall be requested by the intended recipient or the shipper by completion of Section A of PPQ Form 526 (Attachment 1). [NOTE: **THOUGH THE PPQ 526 IS THE CURRENTLY ACCEPTED FORM FOR OBTAINING APHIS-PPQ PERMITS, IT IS PROPOSED THAT A SIMILAR FORM SPECIFICALLY DESIGNED FOR BIOLOGICAL CONTROL ORGANISMS NOT DEEMED TO BE PLANT PESTS BE DEVELOPED BY PPQ (OR ARS) FOR USE BY ARS IN OBTAINING PERMITS FOR IMPORTATION AND INTERSTATE SHIPMENT OF SUCH BENEFICIAL ORGANISMS (PERHAPS FOR PURE CULTURES ONLY), IN PLACE OF THE PPQ-526; SEE ATTACHMENT 2.**] Particularly important information to be included on this form are indications of any host material (plant or arthropod) or soil or other media to be included in the shipments, if any, the APHIS-approved facility to which the shipments are to be initially sent, and the intended final destination of the nematode material. Arrangements must be made with the designated ARS receiving facility for receipt, handling, and transshipment well in advance of intended importations. [NOTE: **THE FOLLOWING STATEMENT AND ATTACHMENT 3 NEED FURTHER STUDY BY A SCIENTIFIC PANEL.**] See Attachment 3 for list of approved ARS receiving facilities for foreign nematodes. The application (PPQ Form 526) should be sent to the regulatory official of the State in which the final destination is located, with a request that Section B of the form be completed and the form be forwarded to APHIS-PPQ. See Attachment 4 for a list of the addresses and telephone numbers of State regulatory officials.

Before PPQ acts on the permit application, they will consult with pertinent nematologists and other scientists of the receiving facilities or other organizations, and State and other regulatory officials as warranted. [NOTE: **THE FOLLOWING STATEMENT IS RETAINED PENDING ACTION BY ARS, APHIS, AND OTHER AGENCIES.**] At this time, the BCAC (see Section V.D) may also be consulted by PPQ. After these consultations, PPQ will either issue a permit for the importation, deny the request, or request additional information prior to making a decision. The permit consists of the completed PPQ Form 526 indicating PPQ approval and any special stipulations in Section C of the form. If importation is approved, PPQ will send the permit to the applicant, with copies to the appropriate quarantine receiving facilities and State regulatory officials and to the BCDC. PPQ will also send appropriate shipment permit labels to the applicant for forwarding to the shipper. The shipment label will be placed on the

outside of each shipment package, to facilitate passage of the shipment through the mails or customs. The shipment labels indicate PPQ approval of the shipment.

Permits for the receipt of live parasitized host arthropods will stipulate initial receipt at approved arthropod quarantine facilities, where the material will be inspected to assure proper packaging, destruction of foreign soil, plant material, and live arthropods after emergence of the nematodes, and/or that no live arthropods or other materials are forwarded unless special permit has been obtained. The material will then be forwarded to the ARS primary nematode receiving facility for examination, study and/or transshipment.

These permits and shipment labels are generally valid only for initial receipt of shipments of foreign material. See Sections V and VI of these Guidelines for procedures for interstate shipments and for field release of imported nematodes. Supplies of PPQ Form 526 permit application are available from APHIS-PPQ or ARS-BCDC.

b. For nematodes for control of arthropod medical and veterinary pests.

An APHIS permit and shipment labels for individual shipments or series of shipments of nematode parasites of medical and veterinary pests from foreign areas shall be requested by the intended recipient or the shipper by completion of VS Form 16-3 (Attachment 5). Particularly important information to be included on this form are indications of any host material (plant or arthropod) or soil or other media to be included in the shipments, if any, the APHIS-approved facility to which the shipments are to be initially sent, and the intended final destination of the nematodes. Arrangements must be made with the designated receiving facility for receipt, handling, and transshipment well in advance of intended importations. [NOTE: THE FOLLOWING STATEMENT AND ATTACHMENT 3 NEED FURTHER STUDY BY A SCIENTIFIC PANEL, PARTICULARLY REGARDING FACILITIES FOR PARASITES OF MEDICAL AND VETERINARY PESTS.] See Attachment 3 for list of APHIS-approved ARS receiving facilities for foreign arthropod-parasitic nematodes.

The permit application (VS Form 16-3) should be sent to VS, at the address shown on the form. Before VS acts on the permit application, they will consult with pertinent scientists of the receiving facility or other organizations, and State and other regulatory officials as warranted. [NOTE: FOLLOWING STATEMENT RETAINED PENDING ACTION BY ARS, APHIS OR OTHER AGENCIES.] At this time, the BCAC (see Section V.D) may also be consulted by VS. After these consultations, VS will either issue a permit (VS Form 16-3a) for the importation, deny the request, or request additional information prior to making a decision. If importation is approved, VS will send the permit to the applicant, with copies to the appropriate quarantine receiving facilities and State regulatory officials and to the BCDC. VS will also send appropriate shipment permit labels to the applicant for forwarding to the shipper. The shipment label will be placed on the outside of each shipment package to facilitate passage of the shipment through the mails or customs. The shipment labels indicate VS approval of the shipment.

Permits for the receipt of parasitized host arthropods will stipulate initial receipt at approved arthropod quarantine facilities, where the material will be inspected to assure proper packaging, and that no live arthropods or plant material are included or forwarded unless special permit has been obtained. The approved material will then be forwarded to the ARS primary nematode receiving facility for examination, study, or transshipment.

There are special requirements in cases where nematodes are to be imported in host arthropods known to feed on human blood or to be vectors of human pathogens. For information about these requirements, ARS personnel must contact the Foreign Quarantine Program, Centers for Disease Control, PHS, USDHHS, Atlanta, GA 30333, or PHS Quarantine Stations at U.S. ports of entry. The VS Form 16-3 may be used to apply for importation permits.

The permits and shipment labels discussed here are generally valid only for initial receipt of shipments in containment facilities. See Sections V and VI of these Guidelines for procedures for obtaining approvals for interstate shipments and for field release of nematodes. Supplies of VS Form 16-3 permit application are available from APHIS-VS or ARS-BCDC.

2. Special Procedures for Importation: Specially-Designated Domestic Receiving Facilities.

APHIS can issue permits and shipment labels on a blanket basis to ARS and other domestic locations approved for initial receipt of shipments of foreign nematode biological control agents for arthropod pests from overseas locations; see Attachment 3 for list of currently-approved facilities. Issuance of these permits and supplies of permit labels will be for shipments of pure cultures of biological control agents, without included plant or host arthropod material, and will be made in response to memoranda explaining in appropriate detail the purposes for which the permits and labels are intended. Such memoranda shall be accompanied by PPQ Form 526 (Attachment 1) [PENDING DECISIONS BY ARS AND/OR APHIS] or "PPQ" Form __ (Attachment 2), with Section A completed by the applicant. Completed application forms and explanatory memoranda will be sent to the appropriate State regulatory official (see Attachment 4) for State approval. Approved forms and memoranda will be forwarded to APHIS-PPQ by the State officials.

The shipment labels are for use for shipments only of nematodes without unsterilized foreign soil, live pest arthropod, or any plant host material. If plant, unsterilized foreign soil, or live arthropod host material is expected to be included in the shipments, a formal permit from PPQ is required, following the general procedures as discussed in Section III.A.1.

PPQ will provide the BCDC and the appropriate State regulatory officials with a record of shipment labels issued, and the recipients of the labels will furnish PPQ, BCDC, and State regulatory offices with a record of material imported under these special procedures on a periodic basis (see also Section V.E of these Guidelines).

3. Shipments to Other Facilities.

The requirement for initial receipt in specially approved facilities may be waived in cases of some shipments entering the United States from Canada and Mexico, and in certain other cases as determined by PPQ. However, a permit for such importations is still required, which will include consultation with appropriate research and regulatory personnel (see Section III.A.1).

B. Shipping Containers for Importation.

Shipping containers will vary according to the requirements of the material to be shipped. However, in all cases, material from foreign sources must be shipped in a container within a container, both of sturdy construction and capable of being sealed. The outer container should be of sturdy impact-resistant material and be enclosed in finely-woven, securely sealed, heavy cloth or canvas, or heavy wrapping paper. The inner container may be of metal, wood, heavy glass, cardboard, or plastic, and should be securely sealed; this container may also be wrapped and sealed in paper, tightly-woven cloth, or other type sealing materials. Approved packing materials necessary for cushioning the inner package within the larger container, include absorbent cotton or processed cotton free of cottonseed, cellulose or plastic materials, excelsior, paper or paper products, sponge rubber, or vermiculite. See Dutky (1974) for other information concerning packaging of beneficial organisms for shipment, and artificial media that can be used in shipments, and Boldt and Drea (1980) for information on shipment of live insects.

Both the inner and outer container and all packing material and media will be destroyed or otherwise treated by incineration, heat or other methods, after contents are removed in the receiving facility, in such a manner that any included pathogens or other organisms are destroyed. Specific procedures will be indicated in facility's Operational Procedures (see Section IV.B).

C. Documentation of Importation.

Because classical biological control projects involve the introduction, release, and establishment in the United States of organisms from other countries, it is important that importations and releases be properly and thoroughly documented.

All shipments of invertebrate biological control organisms from foreign or overseas sources, or shipments from domestic sources that require receipt in containment, shall be accompanied by an AD Form 941 (Attachment 6), with Section I completed in accordance with instructions on the form. Completion of this form provides source, culture, and other information for the recipient of the shipment, and feedback information for the shipper on the results of the shipment. All ARS and other overseas laboratories and personnel engaged in shipping biological control agents to the United States, and all approved domestic ARS receiving facilities for exotic biological control organisms, will be provided by the BCDC with a supply of these forms, and the forms will be issued by them or by BCDC to explorers or other overseas shippers when notified by APHIS of the issuance of an importation permit or shipment labels for individual shipments. In cases where shipments are received without AD-941 type documentation, containment personnel of the ARS receiving facility will be responsible for completion of Section I of the form with information to be obtained from the shipper or other sources.

Whenever possible, ARS collectors and shippers should retain properly preserved specimens of the nematodes shipped and of their hosts/prey, to serve as voucher specimens. Collectors and shippers should provide receiving facilities and the BCDC with information regarding the identity of the organisms shipped and/or their hosts/prey that may in time differ from that given originally on the AD-941 form. See Section V.F of these Guidelines for more information concerning voucher specimens.

IV. Containment Facilities for Receipt of Foreign Arthropod-Parasitic Nematodes; Personnel and Operational Procedures.

All ARS facilities charged with responsibility for the initial receipt and clearance in the United States of foreign nematode biological control agents for arthropod plant or medical and veterinary pests must conform to certain required physical qualifications, and must operate under special permit conditions required by APHIS and pertinent State quarantine regulatory agencies. These permit conditions, which will be monitored by APHIS, will stipulate certain operational and documentation procedures required for operation of the facility in the receipt and handling, and transshipment and field release, of foreign nematode biological control agents.

A. Type of Facilities Required for Initial Receipt of Foreign Nematode Biological Control Agents for Arthropod Plant and Medical or Veterinary Pests.

All ARS facilities to be engaged in initial receipt and transshipment of foreign arthropod-parasitic nematodes are required to be inspected and approved for such purposes by authorized representatives of PPQ, and VS or PHS as appropriate, prior to issuance of an importation permit authorizing such operations. The inspection will be conducted to insure that adequate physical safeguards exist to minimize or eliminate the possibility of escape of organisms from the facility.

These physical safeguards will vary depending upon the type of organisms to be received. For pure cultures of most insect-parasitic nematodes, a Class I Biological Containment Chamber is required, in which any soil received may be removed and autoclaved or otherwise sterilized. [THE FOLLOWING STATEMENTS REQUIRE FURTHER REVIEW BY SCIENTIFIC PANEL.] One exception to this is for steinernematid and other insect-parasitic nematodes that may have associated with them bacteria in genera other than *Xenorhabdus*, in which case a Class II or higher Biological Containment Chamber is required to isolate and characterize the associated bacteria (see Section II.B.1), prior to further handling or shipment of the live exotic nematodes. The following physical features are desirable for all nematode containment facilities approved for initial receipt of exotic nematodes:

- 1) Provision for maximum security area for initial opening of incoming packages of exotic material.
- 2) Means of providing limited access to containment area only to workers directly assigned to containment program.
- 3) Intercommunication system to allow communication with other personnel without need to enter or leave containment area.
- 4) Provision for emergency procedures (in case of power outages, fire, other disasters).
- 5) Direct access in containment to incineration or heat treatment systems for destruction or sterilization purposes.
- 6) Drainage traps and/or settling tanks for preventing the escape of the nematodes are highly desirable, when culture of exotic nematodes is required prior to their clearance for field release or further shipment.

For research on exotic nematodes prior to their clearance for field release, in which culture on arthropods is required, *only domestic host material is to be used*, and the following physical safeguards should be considered to prevent the escape of the exotic nematode in test arthropods during the culture and testing of the nematodes and associated bacteria under containment:

- 1) An anteroom entryway with doors of arthropod escape-proof design.
- 2) Sealed or otherwise arthropod-proof floors, walls, ceilings, windows and doors.
- 3) Sealed or otherwise insect- and mite-proof electrical system, including sealed

floor and wall plugs, switches and lights.

- 4) Heating, cooling, and exhaust systems, preferably closed air systems, fitted with filters adequate to prevent escape of insects and mites.

5) Plumbing system designed to prevent escape of insects, mites, and other arthropods, including adequate screening of floor drains and other accessible drain lines. A trap where waste water from the facility can be sterilized or otherwise treated is highly desirable.

6) Traps effective for various arthropod species placed in anterooms and any other strategic possible escape routes.

7) Provision for special confinement of individual arthropod species to separate cages, chambers or containers within the containment area. [END OF STATEMENTS]

As noted in Section III, if foreign host arthropods must be imported with their nematode parasites, the shipments must be initially sent to approved arthropod biological control quarantine facilities; for physical requirements for these facilities, see Guidelines for Arthropod Parasites, Predators, and Competitors. At these facilities, the exotic nematodes (1) will be emerged for transshipment to the ARS receiving facility, or (2) the material will be examined to determine that all arthropods are dead before being transshipped, or (3) if warranted, the nematodes will be transferred to domestic host material before transshipment. If arthropod hosts known to be vectors of human pathogens must be imported with their nematodes, special physical facility requirements will need to be met. For information about these requirements, ARS personnel must contact the Foreign Quarantine Program, Centers for Disease Control, PHS, USDHHS, Atlanta, GA 30333, or PHS Quarantine Stations at U.S. ports of entry.

If physical safeguards are deemed to be adequate after inspection by APHIS, or following the rectification of any deficiencies found during inspection, and subsequent issuance of an importation permit (see Section III above), APHIS will issue a dated and renewable certificate indicating approval for operation of the facility as a primary receiving center for foreign arthropod-parasitic nematodes. This certificate should be prominently displayed by the approved facility. APHIS officials will conduct unannounced re-inspections of the facility to assure the continuing adequacy of these physical safeguards. State regulatory officials are also authorized to inspect the facilities upon their request.

ARS facilities currently authorized to serve as initial receiving facilities for arthropod-parasitic nematodes are listed in Attachment 3. No other ARS facilities are authorized to receive arthropod-parasitic nematodes directly from foreign sources, with some exceptions as authorized by APHIS (see Section III.A.3).

The approved ARS quarantine facilities will provide address labels and pertinent shipping instructions, including instructions to airline, post office, and customs officials as appropriate, to ARS and other overseas laboratories and personnel upon request, or to the permittee (applicant) upon notification of issuance of a permit for shipment to be received at those facilities (see Section III.A.1).

B. Facility Personnel and Operational Procedures.

1. Receiving Facility Personnel.

Each approved ARS receiving facility for arthropod-parasitic nematodes will have a designated Containment Officer. These will be appointed by the appropriate ARS official after consultation with the NPS, Research Leaders or Laboratory Chiefs, and Area or Center Directors. The Officer will be thoroughly trained in quarantine philosophy and containment operational procedures for arthropods and arthropod-parasitic nematodes, and will be responsible for assuring that these procedures are followed. Specific responsibilities include:

- a) Maintenance of the physical safeguards of the facility as discussed in Section IV.A.
- b) Adherence to permit, documentation, voucher, and other specifically required procedures or restrictions on types of materials to be received or shipped, as may be required by APHIS and the regulatory agencies of the State in which the facility is located;
- c) Proper confinement of all organisms in the containment areas;
- d) Handling of these organisms, by himself or any worker assigned to the quarantine program, in a manner to prevent escape of organisms;
- e) Obtaining authoritative identification of the nematodes and hosts to the extent as may be required;
- f) Authorizing the release of nematodes from containment after screening; and
- g) Packaging and transshipment of nematodes in such a manner as to prevent their escape during transport.

Ultimate responsibility for the release of nematodes from the containment facility rests with the Research Leader of the facility, who in certain cases may himself be designated Containment Officer.

Other personnel assigned to the containment program will be limited in number, and thoroughly instructed in the operational procedures. A list of personnel authorized access to the containment area will be prepared and prominently posted. All other personnel will be denied access to these areas unless accompanied by the Containment Officer or his designated representative.

2. Operational Procedures.

Each ARS facility approved for initial receipt of exotic insect-parasitic nematodes will prepare specialized operational procedures, which may differ depending on the location, primary mission, physical construction, and staffing of the facility. These operational procedures will be approved by appropriate ARS line and staff officials, and by APHIS and State regulatory officials prior to issuance of an importation permit and certificate authorizing operation of the facility as a containment facility for receipt of foreign nematode biological control agents for arthropod plant pests and/or medical and veterinary pests, whichever may be the case. The approved Operational Procedures will be posted near the entrance of the quarantine/containment area of the facility. APHIS officials will conduct periodic unannounced inspections of the facility to ascertain that these procedures are being followed, and State regulatory officials may also conduct such inspections.

Operational procedures must include:

- a) Permit and approval procedures for importations (see Section III.A), including provision for handling unsolicited shipments arriving without proper permits or approvals, and for following other specific procedures as may be stipulated in the importation permit.
- b) Provisions for assuring maintenance of containment conditions, including limited access to containment areas, and requirements for protective clothing, etc.
- c) Provision for opening of incoming shipments only in special maximum containment areas within the main containment area.
- d) Description of means of destruction or sterilization of shipping containers and packing and other foreign material within containment.
- e) Means for screening in containment of imported material and for elimination of inadvertently, inappropriately, or necessarily included organisms such as plant material, arthropod hosts, soil, or contaminants. In all cases, only healthy domestic host material will be used if required to maintain cultures of nematodes in containment.
- f) Means for obtaining rapid authoritative identification of nematode species received in quarantine, to the extent as may be required, by competent nematode taxonomists. No specimens beyond the F₁ generation should be submitted for identification of the initially received material. Though various sources for taxonomic identifications may be utilized, final confirmation of identifications and, when possible, identification of specimens from living cultures, will be provided by the NL since that laboratory is the principal center for nematode identifications within the USDA. Containment facilities may request advice from NL in establishing their procedures for identification. See Steyskal et al. (1986) (for arthropods) and Nickle et al. (1988) for techniques for specimen preparation and for procedures for submitting specimens for identification.
- g) Detailed protocol to be followed prior to release of exotic nematodes from maximum containment area for further testing as required, or prior to the decision to release nematodes from containment for further shipment or field release. This protocol should include consideration of the known or tested host range and relationships of the species or of the taxonomic group to which it belongs, its potential effect on other beneficial organisms, adequacy of safeguards for elimination of contaminants, adequacy of taxonomic identifications, and other safety considerations listed in Section II.B of these Guidelines. See also Section V of these Guidelines.

- h) Means for storage in containment of the imported nematodes.
- i) Packaging and shipping procedures, in such a manner as to prevent the escape of organisms.
- j) Documentation procedures (see Sections III.C, IV.E, VI and VII of these Guidelines).
- k) Voucher procedures (see Section V.F of these Guidelines).
- l) Provisions for monitoring of the Operational Procedures by the Research Leader or Laboratory Chief of the containment facility.

C. Documentation of Receipt of Imported Material.

The Containment Officer of each approved ARS nematode receiving facility is responsible for completion of Section II of AD Form 941 (Attachment 6), which is to accompany each shipment of foreign material received (see Section III.C of these Guidelines), and for filing and distribution of the copies of this form according to instructions on the form. The Containment Officer is also responsible for assuring that these forms are included in all incoming shipments, or for their preparation if not so included.

A record of all shipments and species received in the receiving facility will be periodically provided to BCDC, APHIS, and the pertinent State regulatory agency, as may be stipulated in the importation permit. (See also Section V.E for additional records to be provided by the receiving facility).

The Containment Officer should retain properly preserved specimens of incoming material, and of original host material, if available, to serve as vouchers representing the exotic material received in the containment facility. See Section V.F for additional information concerning voucher specimens.

V. Release from Containment of Foreign Arthropod-Parasitic Nematodes.

The ultimate responsibility for the release of an organism from containment rests with the Research Leader or Laboratory Chief of the ARS receiving facility, although authority for making this decision may be delegated to a designated Containment Officer under certain circumstances. Procedures and considerations required prior to release from containment are included in the Operational Procedures approved by APHIS (see Sections IV.B.2.g and V.A-F of these Guidelines). The Containment Officer is responsible for: 1) Assurance that safety considerations (see Section II.B) are made prior to release of the organism from containment conditions, or that proper arrangements are made for any additional testing deemed to be required; 2) Documentation procedures involved following release from containment; 3) Preparation of voucher specimens as appropriate; and 4) Assurance that any necessary authorizations for interstate shipment and/or field release of the organism are obtained (see Sections V.B-C below).

A. Safety Considerations and Testing, and Clearance for Removal from Containment.

Included in the Operational Procedures, which are approved by APHIS and the pertinent State regulatory agency, are detailed protocols to be followed prior to release of organisms from containment (see Section IV.B.2.g). These protocols include review, clearance, and testing procedures required prior to release of foreign organisms from containment.

1. Review and Clearance Procedures.

The first step in clearance procedures must be to obtain an authoritative morphological and/or biological identification of the organism, at least to generic level if possible (see Section IV.B.2.f). No live material with insufficiently known host relationships will be permitted to leave containment. The Containment Officer, with the pertinent researcher involved with the organism, will determine clearance for release of an organism from containment by means of a critical review of available ecological and biological information based on the taxonomic identification of the organism and discussions with relevant knowledgeable experts, including taxonomists and biological control research workers. During this review, special attention will be made to the safety considerations listed in Section II.B.2 of these Guidelines. Based on this review of information and discussions, conclusions are reached by the Containment Officer by which the identified nematode is assigned to one of three quarantine clearance categories:

Class A: The nematode is considered dangerous or otherwise unsuited for continued experimentation. All material placed in this category must be destroyed in containment.

Class C: The nematode is considered a promising biological control agent, but specific additional studies are deemed necessary before field release can be permitted. Material placed in this category may be given clearance for consignment to other researchers within the receiving facility or for interstate or other shipment, under permit, to appropriate researchers at other facilities of such design as to prevent escape during conduct of the needed studies. See Section V.B for further procedures.

Class D: The nematode is considered safe for field release in the U.S., based on previous release clearance. Nematodes placed in this category may be consigned to non-containment personnel of the receiving facility for field release or shipped interstate following procedures stipulated under Sections V.B-C.

2. Testing under Containment.

Included among the safety considerations listed in Section II.B, is the need for information that may require testing of the nematode under containment conditions. This can include a degree of host-specificity testing of newly imported species to address the following considerations:

a. Potential plant pests or vectors of plant pathogens. Tests to determine this potential will only be necessary in cases in which the biology of the nematode is completely unknown, and plant-feeding nematodes are known to occur in the family to which the species belongs. Tests may be deemed desirable to (1) determine the extent of any potential damage to plants and potential plant "host" range, and (2) assure the elimination of foreign plant pathogens.

b. Potential animal or human pests or vectors of animal or human pathogens. Tests may be deemed desirable to determine whether the nematode is capable of harming humans or animals and the likely extent of such action. This safety consideration applies most particularly in cases where the nematode is associated with dung, and/or attacks other natural enemies of medical and veterinary arthropod pests, with the additional consideration of potential entry of vectors of animal or human pathogens.

c. Potential pests of beneficial or non-target invertebrates.

(1) Potential parasites of beneficial species: Many foreign nematodes may need testing on selected beneficial invertebrates as may be warranted, prior to field release in the United States (see Sections II.B. and IV.B.2.g). Such tests may or may not need to be conducted in containment, at the discretion of the Containment Officer, and with the approval of appropriate regulatory agencies.

(2) Other such host specificity tests may be required to ascertain whether arthropod or other invertebrate species on Federal or pertinent State lists of rare or endangered species will be further endangered by the nematode proposed for introduction.

(3) In the case of nematodes for control of dung-breeding arthropods, the potential effect of the species on other beneficial dung-breeding organisms may require some testing.

d. Research on bacterial associates.

(1) As noted several times in these Guidelines, genera of nematodes of the families Steinernematidae and Heterorhabditidae are known to be associated with symbiotic bacteria identified as *Xenorhabdus* species. Though there may be no reason to suspect otherwise, a check as to the presence or absence of bacterial associates other than *Xenorhabdus* species should be made with newly imported nematode species belonging to these families, and newly imported nematode species of other families in which there may be potential bacterial associates should be similarly checked.

(2) Testing of the effects on selected mammals of any bacterial associates other than those identified in the genus *Xenorhabdus* must be conducted, under containment conditions (Class II or higher Biological Containment Chamber).

In all cases in which the nematode is cultured necessitating the use of arthropod hosts, such cultures must be maintained on domestic hosts, and in strict containment to prevent the escape of nematodes and parasitized hosts.

Some of the information needed concerning nematodes placed in Class C (see Section V.A.1) may include data that must be accumulated by the tests indicated above. Emphasis should be placed on obtaining such information from field studies in the country of origin, if possible, rather than relying solely on results of laboratory tests. Concomitant laboratory tests as needed may be performed either in the primary containment facility in which the material is initially received, or in secondary facilities to which the species may be subsequently shipped. This decision depends primarily upon the availability of adequate facilities, appropriately experienced personnel, and host materials, and the approval of APHIS and pertinent State officials.

If, following testing of the organism, any doubt remains concerning the propriety of release of the organism from containment, the matter may be placed before a panel of appropriate scientists [PHRASE RETAINED PENDING ARS AND APHIS DECISIONS.] and/or the BCAC (see Section V.D) for arbitration. It is important that any potential harmful effects of a biological control agent indicated by such laboratory tests be critically weighed against the potential beneficial effects of the organism and the evidence obtained from field studies and published information concerning the organism where it occurs in nature.

B. Interstate Shipment from Facilities Engaged in Receipt, Propagation, or Storage of Introduced Arthropod-Parasitic Nematodes.

The intended recipient of live foreign nematodes for control of arthropod pests to be shipped through or otherwise received from ARS containment facilities, or from all other ARS facilities, shall be responsible for ascertaining whether any State approvals for such shipments exist in the State in which the organisms are to be received, and for obtaining those permits as required (see Attachments 4 and 7). If the material is to be field released by the recipient, this intent must be clearly indicated, in which case the Containment Officer of the ARS shipping/receiving facility must ascertain whether the necessary approvals for such release, as noted in Section V.C below, have been obtained before shipment of the organisms can be made.

If a State permit for the shipment is required, a copy of the permit will be forwarded by the proposed shipment recipient to the ARS containment or other facility making the shipment and the shipment(s) may then be made. The Containment Officer or pertinent non-containment personnel will maintain a file of such State approvals, and will provide copies to APHIS and BCDC.

Arrangements for State approvals and/or APHIS permits for field releases must be made well in advance of intended shipments, to prevent the loss of valuable live materials while awaiting approval procedures.

All foreign biological control agents shipped from ARS containment facilities will: 1) be packaged in containers designed to prevent breakage or escape of the organisms during transport (see Section III.B); 2) have a PPQ shipping permit label authorizing interstate shipment affixed to the outside of the package, and 3) be accompanied by shipping record forms (see Section V.E).

APHIS-approved ARS containment receiving facilities may obtain a supply of "courtesy" shipping labels from APHIS for use for shipments of pure cultures of nematode biological control agents under the permit issued for containment operation (see Section IV), for shipment to States not requiring a permit. These shipping labels will not be used for cases in which live host materials (arthropod pests) are to be included in the shipments; in these cases, specific APHIS-issued permits and permit labels are required. No interstate shipments will be made by ARS Containment Facilities except under the conditions stipulated in the facility's importation permit received from APHIS for its operation.

Appropriate regulatory agencies in the State in which the containment facility is located will be provided periodically with a written report of interstate shipments of imported nematodes made by the facility, and the regulatory agencies of all other States to which shipments have been made will routinely be informed periodically in writing of the recipients and contents of all shipments made to their States by ARS containment and pertinent non-containment facilities. APHIS and BCDC shall be similarly informed. The Containment Officer(s) shall be responsible for such notification for ARS containment facilities.

C. Approval and Permits for Field Release of Foreign Arthropod-Parasitic Nematodes.

1. General Requirements.

Specific approval procedures for field release of foreign nematode biological control agents for arthropod pests that have been cleared for release from containment under procedures indicated in Section V.A above, will include: a) A requirement for State approval and an APHIS permit for the initial field release of an exotic species in the United States, which may require submission of an Environmental Assessment; b) A requirement for an APHIS permit and State approval for initial field releases of the approved foreign organism in States having regulations requiring such permits or approval, or in States whose regulatory agencies have formally requested notification prior to incoming shipments or releases of exotic organisms; and c) Proper documentation of all initial and subsequent field releases of foreign organisms, including periodic notification of APHIS, BCDC, and pertinent State agencies. The Research Leader and other involved ARS personnel at ARS facilities proposing to release foreign biological control agents for field testing or establishment are responsible for adherence to these procedures.

All applications for State approvals and APHIS permits for field release of foreign nematode biological control organisms for arthropods for field testing or establishment shall be initiated by use of PPQ Form 526 (Attachment 1), [FOLLOWING PHRASES RETAINED PENDING DECISIONS BY ARS AND/OR APHIS.] if the biological control organism to be released or shipped is considered by APHIS to be a plant or veterinary pest, or live host/prey organisms are to be included in the release or shipment, or PPQ/ARS Form __ (see Attachment 2), if only biological control organisms not considered plant or veterinary pests are to be included in the shipment or release. [END OF RETAINED PHRASE - SEE ALSO NOTE IN SECTION III.A.1 ABOVE].

2. Federal and State Regulations.

Provisions must be made to meet the requirements of certain Federal and State regulations impacting the introduction of exotic organisms for biological control of pests. The Federal regulations involved, in addition to the Plant Quarantine Act (PQA) and Federal Plant Pest Act (FPPA) already mentioned in these Guidelines as regulating the importation and movement of live organisms, include the following: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the National Environmental Policy Act (NEPA); the Endangered Species Act (ESA); and possibly the Federal Food, Drug, and Cosmetic Act (FFDCA). The ARS Research Leader, Containment Officer, and involved researchers, are responsible for adherence to the requirements of regulations under these Acts as noted below.

FIFRA: Under this Act, which is administered by the Environmental Protection Agency (EPA), all biological agents used for control of pests are classified as pesticides, and thus their movement and use is regulated by EPA. EPA has exempted from regulation under FIFRA invertebrate biological control organisms, including nematodes, on the grounds that they are adequately regulated by the USDA, primarily by APHIS under the PQA and FPPA and associated regulations.

NEPA: Under this Act, all Federal or Federally-supported agencies must consider the environmental impact of major actions that may significantly affect the quality of the human environment in the U.S. USDA agencies interpret this to mean that, with certain exceptions, an Environmental Assessment (EA) is required for the initial field release of exotic biological control agents in the U.S. That is, an environmental risk analysis must be applied in such actions by ARS (ARS, 1986), and for the issuance of Federal permits by APHIS for the initial field release of introduced plant pests or potential plant pests. [THE FOLLOWING SECTIONS ARE RETAINED PENDING DECISIONS AND ACTIONS BY ARS AND APHIS (AND ATTACHMENTS 8-12 NEED CONSIDERATION BY SCIENTIFIC PANEL).] A proposed list has been prepared of beneficial organisms that offer little or no risk of having significant adverse effects on the quality of the environment, and thus are exempt from this requirement (see Attachment 8). The criteria for excluding these organisms from the EA requirement are listed on Attachment 9. The list of exempted organisms may be amended by application to the ARS and/or APHIS Administrators. APHIS may issue permits for the initial release of the types of organisms represented on the list without preparation of a formal EA.

For initial field release of organisms *not* exempted from a formal EA requirement, environmental assessment protocols have been prepared, the complexity of which vary with the level of risk involved. Attachments 10 and 11 present formats for providing information required for developing an EA required prior to issuance of a permit for initial release of non-exempted organisms. Attachment 12 provides the criteria used to derive these protocols. In cases where the level of risk is high, an Environmental Impact Statement (EIS) would be required. However, for non-exempted arthropod-parasitic nematodes, the abbreviated format (Attachment 10) may generally be used. Either APHIS or ARS scientists or other officials will prepare the environmental documents required to obtain an APHIS permit for initial release. See Section V.D for the role of the BCAC in these procedures. [END OF RETAINED SECTIONS]

ESA: This Act, administered by the Fish and Wildlife Service (FWS) of the USDI, concerns the impact of Federal actions on native endangered and threatened animals (including arthropods) and plants in the U.S. The safety evaluations noted in Sections II.B.2.b and V.A.2.h are designed to meet these concerns. Comments on these concerns and results of any test results related to them should be noted on the permit application or EA protocol document.

FFDCA: This Act, administered by the Food and Drug Administration (FDA), concerns the adulteration of food products by "filthy" substances, including insects or insect-related components. This Act impacted on the use of arthropod natural enemies to control pests in stored food products; these are considered pesticides and are subject to the requirements for tolerances under FFDCA. However, as noted above, these kinds of pesticides have been exempted from registration requirements under FIFRA. The EPA, with the concurrence of the FDA and USDA, has now proposed to have exempted from the requirement of a tolerance certain arthropods used in control of pests of stored products (EPA, 1991). When applying for a permit for the initial release of any nematode natural enemy for use in stored products, which are not so exempted from requirement of a tolerance, an evaluation of its potential as an adulterant of foodstuffs must be made, and comments on this evaluation should be made on the permit application or EA protocol document.

Several States have laws and regulations regarding environmental policy and/or endangered species within their boundaries, similar to NEPA and ESA. In addition, certain States have regulations requiring permits or approval prior to shipment or release of organisms within their borders, or have otherwise formally requested notification prior to such importations or releases (see Attachment 7). Knowledge of and adherence to pertinent State regulations are responsibilities of the involved ARS Research Leader, Containment Officer, and other involved researchers prior to the initial and subsequent field releases of biological control organisms in the U.S.

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY EITHER ARS AND APHIS, OR BOTH (AND ATTACHMENTS 9-12 NEED REVIEW BY SCIENTIFIC PANEL)]

3. Initial Releases of Foreign Arthropod-Parasitic Nematodes in the United States.

Prior to initial field releases of new foreign nematode biological control agents for arthropod pests in the United States, appropriate State approval(s) and an USDA permit must be obtained by the ARS containment facility or other facility proposing to make the initial release. All applications for State approvals or USDA permits for field release or interstate shipment shall be initiated by use of PPQ Form 526 (see Attachment 1), if the biological control organism to be released or shipped is considered by APHIS to be a plant or veterinary pest, or live host/prey organisms are to be included in the release or shipment, or by use of PPQ/ARS Form __ (see Attachment 2), if only biological control organisms not considered plant or veterinary pests are to be included in the shipment or release. [SEE NOTE IN SECTION III.A.1 ABOVE].

Section A of the form will be completed by the facility indicating the intent to field release the biological control agent in the State, and the form will be sent to the pertinent State regulatory agency (see Attachment 4), in which the release is proposed along with an appropriate environmental document if required (see comments below and NEPA requirements above). If an EA is deemed not to be required, it must be documented on the permit application that criteria for exclusion of the organism from the EA requirement have been met (see Attachment 9). State approval will be indicated in Section B of the form, and the form will be forwarded by the State official to APHIS for completion of Section C indicating approval or disapproval of the release.

If an EA is required, there are two possible scenarios:

(1) An appropriate EA protocol document (see NEPA requirements above and Attachments 10-12) will be prepared by the permit applicant and included with the appropriate permit application form when submitted to the State regulatory official in which the initial field release is intended. State approval will be indicated in Section B of the form, and the form will be forwarded by the State official to APHIS, where the document will receive an in-house review in APHIS, and/or by an *ad hoc* panel of appropriate scientists or the BCAC as may be requested. After a favorable review, APHIS will prepare an EA and, if this results in a Finding of No Significant Impact (FONSI), APHIS-PPQ will complete Section C of the permit application form. PPQ will return the completed form (the permit) to the applicant, with copies to the involved Containment Facility (if this differs from that of the applicant), and to the BCDC and the pertinent State regulatory agency. The permits, valid for 5 years, may be renewed for another

5-year period, after which no further permits for release of the permitted organism in that State shall be required. The Containment Officer shall be responsible for permit renewals.

(2) For the second option, the ARS researcher proposing the initial U.S. field release of an introduced biological control agent will submit the appropriate EA protocol documents (see Attachments 10-12) to the pertinent ARS office for review. A FONSI will subsequently be prepared by ARS which will be then be included with the permit application form when sent to APHIS via the appropriate State regulatory agency. APHIS-PPQ may then issue the permit and send copies as in option 1.

Though not required in the EA, it is recommended that studies of the "native" nematodes affecting the target arthropod and their close relatives in the initial and subsequent release areas be conducted prior to release of the foreign organism, in order that the establishment and spread of the introduced organism, and any impacts on non-target organisms, may be better documented.

[END OF RETAINED SECTION REQUIRING DECISIONS BY ARS AND/OR APHIS.]

4. Subsequent Releases of Foreign Arthropod-Parasitic Nematodes.

Completion by ARS Containment Facilities or other shipping/releasing facilities of Section A of the appropriate permit application form for State regulatory agencies is also required for subsequent releases of the same organism in additional States, if those States require permits or prior approval for such releases (see Attachment 7). Unless the State requires or requests an APHIS permit (completion of Section C of the form) or such permit is otherwise required, the form may then be returned to the shipping/releasing facility by the State regulatory agency. The Quarantine Officer or pertinent personnel at other facilities will maintain a file of such State approvals, and will supply copies to APHIS and BCDC. If an APHIS permit is required or requested by the State, the permit application form will be forwarded by the State official to APHIS. Based upon prior release approval and State recommendation, APHIS will complete Section C and distribute copies of the completed form (the permit) as above.

For certain initial releases in the State in which the ARS Containment Facility is located of organisms exempted from the requirement of an environmental assessment, or for which previous release approval has been obtained, PPQ and/or State approval *may* be obtained on the same form used for requesting importation permits (see Section III.A), by indicating the intent to release on the form when first submitted. In certain cases, State regulatory officials may elect to issue "blanket authorizations" for releases of specified biological control agents, in consultation with the Containment Facility and APHIS. In other cases, telephone approvals may be obtained as required in emergency situations; these should be documented in writing as soon as possible. In other cases, State or APHIS officials may elect to request an opinion on proposed releases from BCAC (see Section V.D).

After permits are obtained for their initial releases, no other prior action, except permit renewal as noted above, is required for subsequent field release of foreign biological control agents in States for which permits have been obtained. However, appropriate regulatory agencies in all States in which releases are made shall routinely be informed periodically in writing of all releases of exotic species made within their boundaries by ARS personnel. APHIS and BCDC shall also be similarly informed.

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY EITHER ARS AND APHIS, OR BOTH.]

D. Interagency Biological Control Advisory Committee (BCAC).

The BCAC is an interagency advisory group proposed to be established to provide technical support and advice to ARS and/or APHIS, upon requests from PPQ, State regulatory officials, or biological control research workers: (1) in evaluating risks with specific requests for permits to import or release exotic biological control agents; and (2) in establishing criteria for appropriate evaluation of requests for permits involving biological control organisms. The BCAC will not be involved in making regulatory decisions; it will be consulted regarding proposed importations and releases, primarily in regard to environmental safety factors, in cases in which Federal or State regulatory agencies seek further scientific input to make a regulatory decision, and can serve to resolve any substantive disagreements between APHIS and applicants, or upon specific appeal by biological control research workers, etc. See Attachment 13 for an outline of procedures involving BCAC for providing ARS and/or APHIS with such advice, and Sections V.A.2 and C.3 above for specific information in regard to its involvement in quarantine and field release of introduced biological control agents. All communications with BCAC should be addressed to its Executive Secretary.

After final review of information concerning biological control agents assigned to Class C (see Section V.A.1), including information resulting from tests conducted in containment and other facilities, if any doubt remains as to the propriety of release of the organism from containment status, the question may be placed before BCAC for an informal review. This may be done by the Containment Officer of the facility in which the tests were conducted, or by research workers at that or other facilities who are interested in obtaining clearance for such release. Documentary evidence pro and con will be accumulated for presentation to BCAC, together with an explanatory memo stating the position of the involved Containment Facility, and supportive or contradictory memoranda from interested research and regulatory officials. BCAC will respond with a consensus opinion indicating support or lack of support for the proposed quarantine action. If the consensus opinion is favorable, the Containment Facility or other releasing facility can proceed with field release or interstate shipment procedures, in which the BCAC may be more formally involved (see Sections V.B-C).

[END OF RETAINED SECTION.]

E. Documentation of Consignments, Shipments, and Field Releases of Foreign Arthropod-Parasitic Nematodes.

Because classical biological control projects involve the introduction, release, and establishment of organisms from other countries, it is important that importations and releases be properly documented, so that pertinent information on the origin and release of the imported organisms can be made available to other biological control researchers, ecologists, taxonomists, or Federal and State regulatory officials. Sometimes, imported natural enemies are not found to be established in the U.S. until a number of years have passed following the release(s), so records must be maintained on a long-term basis.

All consignments, shipments, and releases made by ARS Containment Facilities will be documented by completion of AD Form 942 (Attachment 14), in accordance with instructions on the form. Section I of the form is to be completed by the Containment Officer, Section II, and Section III if appropriate, by the recipient of the material.

Material cleared for release from containment in accordance with procedures outlined in Section V.A above may be consigned to non-containment status for further study, culture, or field release by containment or by non-containment personnel of the Containment Facility or of other facilities. In cases in which several consignments of material from the same incoming shipment or containment culture, a single AD Form 942 may be used to record the consignments, noting a range of consignment, receipt, and/or release dates in Sections I-III of the form. Further shipments or releases from non-containment cultures established from these consignments from containment will be documented by use of the AD Form 943; see below.

Each shipment from ARS Containment Facilities shall be accompanied by an AD Form 942, with Section I completed. This form provides source, culture, and other information for the recipient of the shipment, and feedback information for the shipper on the results of the shipment. The recipient of the shipment must complete Sections II and III as applicable, and return the specified copies to the Containment Facility.

In cases where the foreign arthropod-parasitic nematodes shipped are not immediately field released, but instead are laboratory cultured for later field release, the person or facility culturing the foreign species is responsible for documentation of all subsequent releases or shipments of that species until the culture is lost or discontinued. In cases in which interstate shipments are made of this cultured material, permits from APHIS may be required as discussed above (Section V.C). Documentation of those shipments by the culturing facility is also required. The AD Form 943 (Attachment 15) is available for use to provide recipients of shipments with source and culture information and shippers with feedback information from the recipients and for documentation of shipments and releases. However, this form need not be used, if a similarly detailed system of providing information and documenting shipments and releases of exotic nematode biological control agents is used and pertinent reports are made available to BCDC.

All ARS Containment Facilities, and BCDC, will be provided with supplies of AD Forms 942 and 943, and will provide, upon request, supplies of these forms to persons and facilities engaged in culture, shipment, release, and recolonization activities.

The Containment Officer of each ARS Containment Facility shall be responsible for assuring proper documentation of consignments, shipments, and/or releases of foreign nematode biological control agents, using AD Forms 942 and 943 as appropriate, and for distribution of the copies of the forms, in accordance with instructions on the forms.

Periodic reports of consignment, shipment, and release activities may be required of the pertinent facilities by PPQ and/or State regulatory agencies.

F. Voucher Specimens.

Retention of specimens representing imported and released material is required in some cases, and is highly recommended in all cases, in order that vouchers relating to the importation and release of exotic organisms in the United States will be available for immediate or future study by taxonomists and biological control researchers. Voucher specimens are needed particularly to document field release of exotic organisms and to permit *ex post facto* comparisons with U.S. field recovered material to facilitate verification of establishments.

Of particular importance are voucher specimens to document:

- 1) The first field release in the United States of a foreign biological control agent by quarantine or other facilities; these voucher specimens should include specimens from each major geographical area (at least from each country) of origin of the released material;
- 2) Subsequent field releases of the same species from new major geographical areas;
- 3) Field releases from long-established laboratory or storage cultures; and
- 4) The first additional field release of a newly imported foreign species if such releases are resumed after a period of three or more years after initial field release.
- 5) Retention of voucher specimens of the original and laboratory arthropod hosts are also highly recommended; see Steyskal et al. (1986) for information on the preparation of arthropod specimens.

Containment Officers are responsible for obtaining representative specimens documenting the various actions noted above, and for their proper preparation and labeling, and for their curation at the Containment Facility. The Containment Officer shall send certain of the prepared specimens to the NL for inclusion in the National Collection of Nematodes; other vouchers are to be retained and curated at the receiving facility. See Nickle et al. (1988) for information on preparation of nematode specimens for the NL. The Containment Officer shall send to the NL with the specimens information on the origin and field release of the material represented by those specimens, and on their taxonomic identity and the name of the person making this determination; this information can be provided in the form of a reference to the file number of the pertinent shipment record form (AD-942 or -943) recording the release (see Section V.E). The NL will be responsible for providing the specimens with distinctive Voucher Specimen labels, with the information as noted above.

Additional voucher material representing newly imported or newly cultured material may be required from time to time. It is recommended that all containment facilities and facilities engaged in culture activities retain properly prepared and labeled specimens documenting all importations, releases, cultures, or field recoveries, of imported nematodes, and of their original and subsequent laboratory and field arthropod hosts, for reference purposes.

VI. Interstate Shipment of Native or Naturalized Nematode Biological Control Agents for Arthropod Pests for Research.

All ARS facilities and personnel engaged in the field-collection or laboratory culture of native or naturalized (i.e., established exotic) nematode biological control agents for shipment to other States or U.S. Territories for research purposes shall be responsible for ascertaining and adherence to quarantine and other requirements of the States or Territories to which the living material is to be sent (see Attachments 4 and 7). State or Territorial approvals or APHIS permits are required for such shipments only if so stipulated by State or Territorial requirements. These approvals or permits shall be obtained by the intended recipients in the same manner as indicated in Section V.C of these Guidelines. No APHIS shipping labels are required, except as required by pertinent State or Territorial regulations.

All ARS facilities engaged in interstate shipment of living laboratory cultured or field-collected naturalized exotic nematode biological control agents for arthropod pests for research purposes will maintain a record of such shipments, including records of origin, dates of shipment, and recipients, and will provide such records to BCDC and APHIS on an annual basis. State or Territorial regulatory agencies may also request annual notification of shipments made to facilities or personnel within their boundaries. The AD Form 943 (Attachment 15) is available for use by ARS facilities for providing information to the recipient and obtaining feedback information, and for documenting the shipments and/or releases. However, this form need not be used, if a similarly detailed system of providing information and documenting shipments and releases of exotic nematode biological control agents is used and pertinent reports are made available to BCDC.

Although no voucher specimens are required, it is recommended that all facilities engaged in interstate shipment of living native or naturalized nematode biological control agents maintain voucher specimens to document the shipments for possible future reference.

VII. Export of Nematode Biological Control Agents for Arthropod Pests to Other Countries for Research.

All ARS domestic and overseas facilities and personnel making shipments of living nematode biological control agents to foreign countries for research purposes will determine whether or not quarantine regulations exist in the country to which the shipment are to be made, including any requirement for quarantine entry permits, and are responsible for adherence to those regulations, if any.

All shipments to foreign countries shall be shipped in containers designed to prevent escape of organisms. Host materials (arthropod or plant) or unsterilized soil will not be included in the shipments unless absolutely required, and unless specific approval for such inclusion is obtained from the foreign government.

[STATEMENT RETAINED PENDING DECISIONS BY ARS AND APHIS] Although not legally required, it is recommended that an APHIS shipping label be affixed to the outside of the package near the address labels, together with the foreign permit label, if applicable. These shipping labels may be obtained from ARS-BCDC, who will issue the labels only after receipt of documentary evidence that all foreign quarantine regulations have been met or that there are no quarantine regulations (e.g., photocopies of permits or relevant correspondence). [END OF STATEMENT]

As a courtesy and for the information of the foreign recipient, shipment record forms (AD Form 941) (Attachment 6), with Section I completed, should accompany each shipment, with a request that Section II of the form be completed, and the form returned to the sender. The sender is responsible for distribution of copies of the form in accordance with instructions on the form.

Although no voucher specimens are required, it is highly recommended that the sender of shipments to foreign countries retain such specimens to document the contents of the shipments for possible future reference.

VIII. Recommended References.

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Way, M. J. 1990. Biological Control Introductions: A review and justification of the need for a code of conduct with a recommended code for consideration at a FAO expert consultation. Mimeo draft, International Institute of Biological Control, Ascot, 34 pp. + 18 Annexes, November, 1990.

PPQ Form 526: Application and Permit to Move Live Plant Pests or Noxious Weeds

SEE NO. 1 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed PPQ/ARS Form __: Application and Permit to Move Living Beneficial Organisms

SEE NO. 2 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

List of ARS Biological Control Quarantine Facilities Proposed to be Approved for Initial Receipt of Foreign Nematode Biological Control Agents for Arthropod Pests

TO BE PREPARED

List of Plant Regulatory Officials of U.S. States and Territories, Canada, and Mexico

SEE NO. 3 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

VS Form 16-3: Application for Permit to Import or Transport Organisms or Vectors

SEE NO. 4 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

AD Form 941: Biological Shipment Record - Foreign/Overseas Source

SEE NO. 5 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries

SEE NO. 13 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES
TO BE PREPARED

Proposed List of Invertebrate Biological Control Agents Exempted from the Requirement of a Formal Environmental Assessment

SEE NO. 8 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

[THIS LIST NEEDS FURTHER REVIEW BY PANEL OF NEMATOLOGISTS
(Particularly in Regard to Rationale Section)]

Proposed Criteria for Exemption of Invertebrate Biological Control Agents for Arthropods from the Requirement of a Formal Environmental Assessment for Field Release

SEE NO. 9 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

[THESE CRITERIA NEED REVIEW BY PANEL OF NEMATOLOGISTS
(Particularly in Regard to Criteria Specific to Nematodes)]

Draft Guidelines (B, page 31)

Proposed Abbreviated Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Exotic Invertebrate Biological Control Agents of Arthropod Pests: Short Format

SEE NO. 10 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

[THIS DOCUMENT NEEDS REVIEW BY PANEL OF NEMATOLOGISTS
(Particularly in Regard to Data Items Specific to Nematodes)]

Proposed Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Biological Control Agents: Long Format

SEE NO. 11 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Criteria for Biological Control Agents Requiring Either (1) an Abbreviated or (2) a Detailed Protocol Document for Providing Environmental Assessment Information

SEE NO. 12 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

[THESE CRITERIA NEED REVIEW BY PANEL OF NEMATOLOGISTS
(Particularly in Regard to Criteria Specific to Nematodes)]

Proposed Structure and Procedures of the **Proposed** Biological Control Advisory Committee (BCAC)

SEE NO. 7 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

AD Form 942: Biological Shipment Record - Quarantine Facility

SEE NO. 14 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

AD Form 943: Biological Shipment Record - Non-Quarantine

SEE NO. 15 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

**Proposed ARS Guidelines for
the Importation, Interstate Movement, and Field Release in the United States
of Foreign Arthropods and Nematodes for Biological Control of Weeds,
and for the Interstate Movement and Export of Foreign and Native
Arthropod and Nematode Natural Enemies of Weeds ¹**

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Attachments

1. Organizational Abbreviations, Addresses, and Telephone Numbers
2. Charter of the Technical Advisory Group on Introduction of Biological Control Agents of Weeds, and List of its Organizational Members
3. PPQ Form 526: Application and Permit to Move Live Plant Pests and Noxious Weeds
4. List of ARS Biological Control Quarantine Facilities Approved for Receipt of Foreign Arthropods and Nematodes for Biological Control of Weeds
5. List of Plant Regulatory Officials of U.S. States and Territories
6. **Proposed** Guidelines for U.S. Importation of Exotic Natural Enemies of Weeds from Canada
7. AD Form 941: Biological Shipment Record - Foreign/Overseas Source
8. Form ARS-748: Identification Request
9. An Example of a Quarantine Operational Procedures Document
10. **Proposed** Abbreviated Protocol Document for Providing Data for Environmental Assessments for Initial Field Release of Biological Control Agents of Weeds: Short Format
11. **Proposed** Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Field Release of Biological Control Agents of Weeds: Long Format
12. **Proposed** Criteria for Biological Control Agents for Weeds Requiring Only an Abbreviated Protocol Document for Providing Environmental Assessment Information
13. List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries
14. Structure and Procedures of the **Proposed** Biological Control Advisory Committee (BCAC)
15. AD Form 942: Biological Shipment Record - Quarantine Facility
16. AD Form 943: Biological Shipment Record - Non-Quarantine
17. **Proposed** Structure and Procedures of the U.S. National Voucher Collection for Introduced Beneficial Arthropods

¹ Original draft prepared by J. R. Coulson from 1978 draft material by L. A. Andres (ARS); revisions by P. C. Quimby, N. E. Rees, J. L. Birdsall and J. R. Coulson, following review by Working Session participants (see Appendix 1) in January, 1991; further comments incorporated from later reviews by J. Antognini (ARS), and R. D. Goeden (University of California).

I. Intent and Scope of these Guidelines.

Importations of natural enemies from other countries for biological control of weeds in the continental U.S. began in the 1940s with the highly successful control of the introduced weed St. Johnswort or Klamath weed. During subsequent years, procedures were developed by U.S. researchers to assure that such importations were conducted with the maximum possible safety to U.S. agriculture and environment. In the 1970's, the USDA Agricultural Research Service (ARS) Working Group on Natural Enemies of Insects, Weeds, and other Pests was formed, which began the process of codifying these guidelines for ARS scientists. These current Guidelines, which are the result of input from many ARS and other scientists, are intended to provide detailed procedures required for the continued safe importation, interstate shipment, and field release of foreign invertebrate, particularly arthropod and nematode, natural enemies of weeds for biological control research and development programs in the United States. These procedures are designed to insure that every reasonable precaution will be taken to contain and prevent the escape or release of organisms that are injurious to agricultural, horticultural, or forestry commodities, man and domestic animals, or other beneficial organisms, or that are otherwise detrimental to the environment.

Organisms for which these Guidelines are intended include species of the Phyla Nematoda and Arthropoda (particularly the Classes Insecta and Arachnida) that are to be studied or utilized as natural enemies in the suppression of populations of weedy plants. Separate Guidelines exist for the importation of pathogens for control of weeds, for the importation of various other invertebrates and pathogens for control of invertebrate pests, and for pollinating invertebrates.

These Guidelines also include procedures for the interstate movement and export of native or naturalized biological control agents for weeds.

Some organizational abbreviations used in these Guidelines are as follows (see Attachment 1 for pertinent addresses and telephone numbers):

- APHIS - Animal and Plant Health Inspection Service, USDA
- ARS - Agricultural Research Service, USDA
- BCAC - Interagency Biological Control Advisory Committee **Proposed**
- BCDC - Biological Control Documentation Center, ARS
- EPA - Environmental Protection Agency
- FWS - Fish and Wildlife Service, USDI
- NL - Nematology Laboratory, ARS
- NPS - National Program Staff, ARS
- PPQ - Plant Protection and Quarantine, APHIS
- SEL - Systematic Entomology Laboratory, ARS
- TAGIBCAW - Technical Advisory Group on the Introduction of Biological Control Agents of Weeds
- USDA - United States Department of Agriculture
- USDI - United States Department of Interior

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II. Summary of Procedural Policies and General Safety Considerations.

A. Summary of Procedures for Importation, Interstate Shipment, Field Release, and Export of Arthropod and Nematode Natural Enemies of Weeds.

The Plant Quarantine Act of 1912 and the Federal Plant Pest Act of 1957 prohibit the importation and movement of plant and animal pests, pathogens, vectors, and articles that might harbor these organisms, unless authorized by the U.S. Department of Agriculture (USDA). The National Environmental Policy Act of 1969 (NEPA) contains provisions that impact upon the release of exotic organisms into the environment. Regulations under these Acts pertaining to biological control of weeds agents are enforced by the Plant Protection and Quarantine Programs (PPQ) of the Animal and Plant Health Inspection Service (APHIS) of the USDA.

The determination of the adequacy of quarantine (or containment) facilities for receipt and laboratory testing of foreign organisms, and of the technical competence of investigators, is the responsibility of APHIS-PPQ and pertinent State Departments of Agriculture. Determining the requirements that must be met for introduction of such organisms into quarantine or into the field is also their responsibility. A Technical Advisory Group on the Introduction of Biological Control Agents of Weeds (TAGIBCAW) has been established to provide advice to biological control researchers and APHIS during the course of biological control of weeds programs involving foreign biological weed control organisms. APHIS and TAGIBCAW want to assure that safety considerations such as those listed below are made prior to importation or field release of foreign biological control organisms in the United States. [NOTE: THE FOLLOWING STATEMENT CONTAINS A PROPOSAL AND IS RETAINED PENDING ACTION BY ARS, APHIS, AND OTHER AGENCIES.] Also, an interagency Biological Control Advisory Committee (BCAC) has been (proposed to be) established to provide technical support and advice to APHIS and involved researchers, upon request, on proposed importations and releases in the United States. [CLOSE OF STATEMENT]

Certain of the safety considerations listed below must be made during the overseas exploration phases of a biological control introduction program, i.e., before importation of the proposed biological control agent, while others can be made during the domestic quarantine phase of the introduction program. The procedures detailed in these Guidelines are designed to assure that such considerations are made and necessary precautions are taken.

It is highly recommended that the following references be studied in conjunction with these Guidelines: Klingman and Coulson (1982-83); Lima (1983); Turner (1985); Coulson and Soper (1989); Wapshere (1989); Harris (1990); Way (1990); Howarth (1991); and Fisher and Andres (in press).

The more important conditions required for the importation and release of foreign arthropods and nematodes for control of weed pests as reflected in these Guidelines can be summarized as follows:

- 1) Prior to initiation of a biological control of weeds program, investigations will be made and advice received on the weediness of the plant targeted for biological control and on potential conflicts of interest in regard to that plant. See Section III.

- 2) In most cases, a considerable amount of information about the weed's foreign natural enemy proposed for introduction must be obtained overseas prior to its importation into the U.S. See Sections IV.A-B.

3) All foreign organisms shipped to the United States or later shipped interstate must be shipped in containers meeting USDA standards, and must be shipped with APHIS approval. See Sections III.B-C and V.C.

4) Foreign arthropods and nematodes for biological control, with few exceptions, must be received in quarantine (containment) facilities approved by APHIS, where necessary testing prior to release must be conducted under strict quarantine conditions, and where all material deemed to be of potential hazard or detriment is to be destroyed. A trained Quarantine Officer will be duly appointed who will be responsible for all quarantine operations. See Sections V.A-C.

5) Authoritative identifications of the foreign organisms and of their host plants are required prior to their importation in most cases, and certainly prior to their release or consignment from quarantine, and all safety considerations as listed below must be made prior to such release/consignment. See Section VI.A.

6) Review of research results and evaluation of proposed importation and/or release of biological control agents by an interagency review group(s), and, for releases, by Canadian and Mexican officials. See Sections IV.C and VI.C.

7) Release from quarantine and field release formalized through PPQ and pertinent State permit procedures, which involve formal Environmental Assessments. See Section VI.C.

8) Voucher specimens to document the field release of exotic organisms are required, and certain other documentary procedures are to be followed, during which APHIS and other officials are to be kept informed of all releases and shipments. See Sections IV.D, V.D, and VI.D-E.

9) For interstate shipment and export of weed-feeding arthropods and nematodes, adherence to PPQ permit procedures and quarantine requirements of the pertinent States and Territories of the United States and foreign countries is necessary prior to the shipment of the beneficial organisms into those States, Territories, or countries. See Sections VI.C.3, VII and VIII.

B. Safety Considerations Required for Importation and Field Release of Foreign Arthropods and Nematodes for Biological Control of Weeds in the United States.

The following safety considerations, discussed further throughout these Guidelines, must be evaluated prior to considering the importation or release of foreign arthropods and nematodes for biological control of weeds into the United States:

1. Protection Against Entry of Plant Pathogens or Weeds.

a. Entry of host plant material must be restricted as much as possible; if entry of plant material is required, it must be destroyed in quarantine.

b. Potential invertebrate vectors of plant pathogens need study to assure elimination of foreign pathogens of potential hazard to non-target plants.

2. Protection Against Entry of Invertebrate Plant Pests.

a. Investigations must be made to determine whether a potential conflict of interest exists as to the weediness of the plant proposed for biological control; if any such conflicts cannot be resolved, such plants shall not be targeted for biological control by the use of introduced foreign invertebrate organisms.

b. Entry of extraneous exotic invertebrate material must be restricted as much as possible; if entry of such organisms is required, they must be destroyed in quarantine.

c. See also item 4b below.

3. Protection Against Entry of Arthropods Hazardous or Nuisances to Humans or Domestic Animals.

a. Knowledge is required that the biological control agent will not harm vertebrates.

4. Protection Against Entry of Invertebrates and Other Organisms Inimical to Native or Other Introduced Non-Target Organisms.

a. Provisions are required for the elimination of parasites and pathogens of the introduced biological control agent, particularly those which may severely effect other native or introduced invertebrates in the United States.

b. The potential effect of the biological control agent on non-target organisms, e.g., native plants of economic and ecologic value, endangered and threatened plant species, pollinators, and other biological control agents of arthropods and weeds, must be considered; host specificity studies are required to determine the safety to non-target plant species.

The degree of risk involved as to potential detrimental effects of a natural enemy of a weed that may also attack non-target organisms (as in 3 and 4 above) should be weighed against the potential beneficial effects of the natural enemy proposed for release. Emphasis should be placed on obtaining information needed from field studies in the country of origin, as much as may be possible, rather than entirely on laboratory tests.

III. Determination of the Suitability of a Weed for Biological Control.

If a plant species is newly proposed as a target of a biological control program involving the introduction of foreign control agents, and no agents have previously been intentionally introduced for its biological control, a proposal to this effect should be made to the Technical Advisory Group on Introduction of Biological Control Agents of Weeds (TAGIBCAW). See Attachment 2 for the charter of the TAGIBCAW and a list of its organizational members. ARS researchers must also submit such a proposal to the USDA-ARS National Program Staff (NPS) for preliminary approval.

The proposal should include the following information:

A. Biological Factors:

1. Identification of the candidate weed, including full scientific name, classification, and sufficient characterization to allow unambiguous recognition.
2. Geographical distribution of the candidate weed, including information on probable area(s) of origin and any knowledge of the existence of various strains of the plant.
3. Digest of the known ecology and biology of the candidate weed including growth characteristics and documentation of its weediness.
4. History of the candidate weed since its introduction to the North American continent.
5. History of the candidate weed in other countries where it was introduced.

B. Economic Factors:

1. Estimation of the current type and level of damage caused.
2. Costs of alternative control measures, including frequency of operations needed.
3. Forecast of the likely future extent of the problem based on the rate of expansion, if no action is taken.
4. Beneficial values or uses of the candidate weed in the U.S., Canada, Mexico, or Central America, or any information that the candidate is valued by a part of the community.
5. Comparison of the competition pressure of the candidate weed versus the potential pressure of introduced natural enemies on native species.

C. Potential Control Factors:

1. List of any records of natural enemies, highlighting species or groups likely to be good candidate biological control agents.
2. Biological control results achieved on any plant species related to the candidate weed.
3. Preliminary list of proposed plants to be included in host specificity studies.

The TAGIBCAW will provide the proposer with comments on the importance of the weed in relation to the agency affiliations of its members and on whether a conflict of interest over its control may exist in North America. If a potential conflict of interest does exist, the TAGIBCAW may advise as to the type of data that might be helpful in resolving the conflict, or if the conflict is deemed insurmountable, the TAGIBCAW will so indicate and APHIS-PPQ may deny approval of the proposed program. The TAGIBCAW will indicate what considerations must be given to other plant species during the testing phase of an approved program to establish specificity and safety of proposed biological control agents.

IV. Selection and Initial Importation of Foreign Arthropods and Nematodes for Biological Control of Weeds.

Once approval for a biological control of weeds program has been obtained from NPS and TAGIBCAW, ARS research workers should obtain as much pertinent information as practical concerning potential foreign biological control agents proposed for importation prior to their shipment to the United States. In the case of biological control of weeds agents, this information should include an identification of the agent and its host(s), and pertinent biological information based on literature reviews and field studies, to assess the potential usefulness and safety of the candidate biological control agent.

Precautions as indicated in this Section of these Guidelines are designed to provide for the safe shipment and receipt for research in the U.S. of all foreign arthropod and nematode biological control agents for weed pests. Pertinent information is required to be accumulated overseas prior to clearance of the biological control agent for importation and more may be required for its consignment/release from quarantine.

After preliminary studies in the U.S., necessary overseas research, and permit procedures discussed below, all potential arthropod and nematode biological control agents for weed pests approved for shipment to the United States from foreign sources must: 1) have appropriate APHIS-PPQ shipping permit labels affixed to the outside of the packages; 2) be shipped in containers meeting certain specifications; 3) be accompanied by specified documentation; and 4) be routed to and received and opened in designated approved primary quarantine facilities (see Section V), with certain exceptions.

Inclusion of host plant, extraneous invertebrate material, or soil in shipments from foreign sources will be limited to those cases in which such inclusion is a necessity. Should unsolicited shipments of potentially useful organisms and/or host material not covered by APHIS permits or authority be received in quarantine, APHIS-PPQ should be notified immediately for post-shipment approval, such material usually to be destroyed after positive identifications in quarantine are made. The TAGIBCAW should also be informed of unsolicited shipments.

A. Literature Surveys and Overseas Studies.

Once approval has been obtained from NPS and TAGIBCAW, potential control agents must be located and identified. This can be done through the following:

1. Detailed literature searches for organisms associated with the target plant, highlighting species or groups likely to be potential biological control agents.
2. Field surveys in native areas of the target weeds, cataloging potential biological control agents according to the nature of their attack on the target weed.
3. Experimental field and laboratory ecological studies, with emphasis on defining the roles of potential biological control agents at selected source areas.

Only in rare cases, will APHIS-PPQ approvals be given for the importation into U.S. quarantine of unidentified and untested living agents for biological control of plants, as these are potential plant pests. Therefore, in most cases, identification of the organism and preliminary host specificity and other tests sufficient to indicate the probable safety of the organism are required to be performed at overseas locations. In all cases, ARS researchers conducting such studies at overseas locations are responsible for knowledge of

and adherence to the quarantine regulations of the country in which tests are to be conducted. These pertain both to the entry and use of exotic test plant species, and the entry and study of exotic invertebrate weed natural enemies and associated materials.

The following type information should be collected on the organisms identified as potential biological control agents:

1. Taxonomic identification of the candidate biological control agent, to include full scientific name, classification, and sufficient characterization to allow unambiguous recognition.
2. Geographical distribution of the candidate agent, including probable area(s) of origin and knowledge of the existence of strains.
3. Studies showing that the candidate agent will readily feed and breed on the target weed.
4. Initial information on the known host range of the candidate biological control agent, to include literature records and results of preliminary screening tests.
5. Life history studies, including information on culturing under laboratory conditions.
6. Information on natural enemies of the candidate agent, including pathogens and parasites, and provisions to effect their elimination from a culture of the agent.
7. Knowledge that the candidate biological control agent will not harm vertebrates.

It may be occasionally necessary for a researcher to request permission to conduct preliminary studies of exotic agents in domestic U.S. quarantine facilities before identification or extensive studies have been performed overseas. As noted in Section IV.C below, these relate only to cases in which permission is requested to import into approved quarantine facilities (a) potential agents with insufficient taxonomic information, for identification purposes, and (b) a candidate agent, fairly well known both taxonomically and biologically, to determine whether it will attack or feed on the strain(s) of the target weed growing in the United States. In these two cases, neither breeding nor extensive host specificity testing is permitted by APHIS-PPQ in quarantine. In these cases an abbreviated report can be submitted to the TAGIBCAW along with an application for an APHIS-PPQ importation permit (see Section C below).

B. Host Specificity Testing.

Host specificity screening tests are required to be conducted on all potential biological control agents for weeds proposed for introduction into the United States. Such tests are usually begun at overseas locations, and completed as may be required in approved domestic U.S. quarantine facilities. The purpose of such tests is to determine the potential host range of the candidate biological control agent without testing numerous plant species of little probability as hosts of the agent. This is done by exposing the candidate agent to plant species selected from a centrifugal (concentric circle) plant matrix. The target weed is in the center of the matrix and representatives from species in the same subgenus as the weed constitute the first ring. Each subsequent ring consists of plants which are less closely related taxonomically to the target weed.

The nature of the host specificity screening tests depends on the target weed and control agent in question. The degree of specificity which needs to be demonstrated and the level of risk which is acceptable depend on the importance of the weed and the presence of non-target species closely related to it in the location where the weed is to be controlled.

In "no-choice" feeding and oviposition tests, agents are isolated in containers with a test plant until the agents either die or feed and/or oviposit. Attempts are also made to determine the degree of effect the agent has on the test plant. For agents which fail the "no-choice" tests, i.e., the tests indicate the agent's potential host range may be unacceptably broad, and in other cases, "multiple choice" testing, which combines the target weed along with the test plant in a container is performed.

The highly artificial conditions of these tests may lead to the rejection of agents which are host specific under field conditions. Therefore, when possible, field tests in the native land of the candidate biological control agent are suggested. Providing there are no restrictions on importing certain test plants into the area, test plants can be placed in a stand of the weed infested by the agent. Observations can then be made on the host range of the agents under these field conditions. It may also be possible to set up a garden of test plants in the agent's area of origin which includes the target weed where the screening can be conducted. It must be strongly reiterated that ARS researchers conducting such studies at overseas locations are responsible for knowledge of and adherence to the quarantine regulations of the country in which tests are to be conducted. These pertain both to the entry and use of exotic test plant species, and the entry and study of exotic invertebrate weed natural enemies and associated materials.

One example of a host specificity testing regime is the centrifugal host specificity screening matrix, which includes tests in the following categories:

1. The target weed and subspecies or biotypes of the target weed.
2. Species in the same subgenus as the weed.
3. Species in various subgenera in the same genus as the weed.
4. Genera in the same tribe ... and so on until only negative results are obtained.
5. Other recorded host plants of the agent no matter how dubious the record.
6. Host plants of species closely related to the agent.
7. Unrelated plants with biochemical or morphological characteristics in common with the target weed.
8. Selected crop, ornamental, and ecologically important plants known to occur in the same geographical area and ecological niches as the target weed.

The following references dealing with host-plant specificity testing are recommended reading: Harris and Zwölfer (1968); Zwölfer and Harris (1971); Wapshere (1974, 1975, 1989); and Schroeder and Goeden (1986). See also Sections VIA-C of these Guidelines.

C. Approvals, Permits, and Shipment Labels for Importation.

The following procedures are required after the selection and preliminary study of a natural enemy overseas in order to import the species for further study in the U.S.

1. General Procedures.

a. Technical Advisory Group on Introduction of Biological Control Agents of Weeds (TAGIBCAW).

See Attachment 2 for the Charter and organizational membership of the TAGIBCAW. After identification and initial study overseas, and prior to initial importation into quarantine facilities in the United States of live biological control agents of weeds, a recommendation from the TAGIBCAW is needed to support an APHIS-PPQ decision regarding issuance of the necessary importation permit. A report on the past and proposed studies on the candidate biological control agent must be submitted to the Executive Secretary of the TAGIBCAW. Sixteen copies of the report are required.

The report should include: (1) information on the facility where quarantine studies will be conducted, and the names and qualifications of the persons who will conduct the quarantine studies; (2) information on the taxonomic identification of the organism and on its distribution, biology, and host specificity determined by studies overseas, as suggested above; and (3) an outline of the proposed quarantine studies which will provide missing information, including a list of the proposed test plants. See Klingman and Coulson (1982-83) for an indication of the kind of data to be included in the report and a suggested report format. This report may be prepared either by foreign or domestic researchers.

If a favorable recommendation from the TAGIBCAW is received, permit application procedures (see Section b below) may be initiated. If the TAGIBCAW recommendation is negative, the researcher may conduct additional studies as may be suggested by the TAGIBCAW and submit a supplementary report addressing the concerns expressed by the TAGIBCAW.

It may be occasionally necessary, in order to facilitate the research, for the researcher to request permission to conduct preliminary studies of foreign organisms in domestic quarantine facilities before identification of the organism or extensive studies are conducted overseas. These relate only to cases in which live material is required (a) of immature stages of potential agents in which adults are to be emerged for identification purposes, and (b) of a candidate agent, fairly well known both taxonomically and biologically, to determine whether it will attack or feed on the target weed growing in the United States. In both cases, neither breeding nor extensive host specificity testing of the organisms is to be requested. An abbreviated report requesting such importations can be addressed to the TAGIBCAW, or can accompany the application for an APHIS-PPQ importation permit (see Section b below).

Sufficient information may occasionally have been obtained from overseas studies or elsewhere to support submission of a request for field release of the organism in the United States without additional studies in quarantine facilities. See Sections V and VI below for pertinent procedures to be followed in these cases.

b. APHIS-PPQ Permits and Shipment Labels.

Following a favorable recommendation from the TAGIBCAW, an APHIS-PPQ permit and shipment labels for shipments of natural enemies of weeds from foreign areas should be requested by the intended recipient by completion of Section A of PPQ Form 526 (Attachment 3). Particularly important information to be included on this form are indications of any host or soil material to be included in the shipments, if any, and the quarantine facility to which the shipments are to be sent. Arrangements must have been made between the shipper and the designated Quarantine Facility for

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quarantine receipt, handling, and studies well in advance of intended importations. See Attachment 4 for a list of approved ARS quarantine receiving facilities, and Section 2 below for special procedures for receipt of exotic weed control agents in non-quarantine facilities in special cases.

The permit application (PPQ Form 526) should be sent to the regulatory official of the State in which the quarantine receiving facility is located, with a request that Section B of the form be completed and the form be forwarded to APHIS-PPQ. See Attachment 5 for list of the addresses and telephone numbers of State regulatory officials.

PPQ will either issue a permit for the importation, deny the request, or request additional information prior to making a decision, for the most part, usually depending upon the prior recommendation of the TAGIBCAW.

The permit consists of the completed PPQ Form 526 indicating PPQ approval and any special stipulations in Section C of the form. If importation is approved, PPQ will send the permit to the applicant, with copies to the appropriate Quarantine Facility, if different from the applicant, the pertinent State regulatory official, and the BCDC. PPQ will also send appropriate shipment permit labels to the applicant for forwarding to the shipper. The shipment label will be placed on the outside of each shipment package to facilitate passage of the shipment through the mails or customs. The shipment labels indicate PPQ authorization for the shipment.

These permits and shipment labels are generally valid only for initial receipt of shipments in quarantine facilities. See Section VI.C of these Guidelines for procedures for obtaining approvals for interstate shipments from quarantine facilities and for field release of biological control agents for weeds. For agents already cleared for field release in the State in which the quarantine facility is located, PPQ and State approvals for field release in that State may be obtained concurrently by indicating intent to release on the PPQ Form 526. Supplies of PPQ Form 526 permit application are available from APHIS-PPQ or ARS-BCDC.

2. Shipments to Non-Quarantine Facilities.

The requirement for initial U.S. receipt of foreign biological control agents for weeds in approved quarantine facilities may be waived in a few cases of shipments entering the United States from Canada. This requirement may also be waived in the case of some subsequent shipments from Canada. See special Proposed guidelines for importations from Canada, Attachment 6; similar guidelines may also be applicable in the case of importation of potential biological control of weeds agents from Mexico. In all cases, APHIS-PPQ permits are required.

D. Shipment Procedures and Containers for Importation.

1. Shipment Procedures.

All foreign organisms shipped to the United States or later shipped interstate must be shipped in containers meeting USDA standards, and must be shipped with APHIS-PPQ authorization. Prior notification by the shipper of impending shipments should be made to the receiving quarantine facility to facilitate planning for space in maximum security and other preparations for receipt of the shipment. Likewise, notification should be made to port inspectors or customs at ports of entry to facilitate clearance of packages.

Procedures overseas for shipment involve the following:

- a. Field collection should be generally from the same area and hosts from which the material tested was obtained, and reproduction of the material in the laboratory should be obtained, if possible.
- b. Authoritative identification to species of the collected or cultured agents should be obtained prior to shipment; see the exception to this requirement noted in Sections IV.A and C above.
- c. In general, only the agent and material essential for its survival during shipment should be included in the shipment. This includes, if possible, a stage of the agent that does not require food during shipment; if entry of host plant material is required, it must be destroyed in quarantine. Likewise, if soil is required for nematodes, specific permits from APHIS-PPQ must be obtained, and the soil must be autoclaved or otherwise sterilized prior to shipment.
- d. The agents should be screened for pathogens and parasites, information about which is obtained during the field collection and testing phases of the overseas studies, and steps taken to assure the shipment is free of such natural enemies, contaminants, and other organisms, as much as possible.
- e. Export permit should be obtained if required by country of origin.
- f. Advance notice of shipment should be provided, as noted above, with full details of routing to the receiver.
- g. Packaging and documentation of the shipment is required, as discussed below.

2. Shipment Containers.

Shipping containers will vary according to the requirements of the material to be shipped. However, in all cases, material from foreign sources must be shipped in a container within a container, both of sturdy construction and capable of being sealed. The outer container should be of sturdy impact-resistant material and be enclosed in finely-woven, securely sealed, heavy cloth or canvas, or heavy wrapping paper. The inner container may be of metal, wood, heavy glass, cardboard, or plastic, and should be securely sealed; this container may also be wrapped and sealed in paper, tightly-woven cloth, or other type sealing materials. Approved packing materials necessary for cushioning the inner package within the larger container, include absorbent cotton or processed cotton free of cottonseed, cellulose or plastic materials, excelsior, paper or paper products, sponge rubber, or vermiculite. See Bartlett and van den Bosch (1964) and Boldt and Drea (1980) for other information concerning packaging of beneficial arthropods for shipment, and Nickle et al. (1988) for precautions regarding contents of shipments of nematodes, particularly regarding shipment in sterilized soil.

The outer package should prominently display the appropriate APHIS-PPQ shipment authorization label and institutional identification, including the address and telephone number of the contact person at the receiving institution. A label stating "Scientific Material - No Commercial Value" is also suggested to be displayed.

Both the inner and outer container and all packing material will be destroyed or otherwise treated by incineration, heat or other methods, after contents are removed in the Quarantine facility, in such a manner that any included pathogens or other organisms are destroyed. Specific procedures will be indicated in Quarantine Operational Procedures (see Section V.C.2).

E. Documentation of Importation.

Because classical biological control of weeds projects involve the introduction, release, and establishment in the United States of organisms from other countries, it is important that importations and releases be properly and thoroughly documented.

All shipments from foreign or overseas sources, or shipments from domestic sources that require quarantine receipt, shall be accompanied by an AD Form 941 (Attachment 7), with Section I of the form completed and copies distributed, in accordance with instructions on the form. This form provides source, culture, and other information for the recipient of the shipment, and feedback information for the shipper on the results of the shipment. All ARS and other overseas laboratories and personnel engaged in shipping biological control agents to the United States, and all approved U.S. or territorial quarantine facilities, will be provided by the BCDC with a supply of these forms, and the forms will be issued by them or by BCDC to explorers or other overseas shippers when notified by PPQ of the issuance of an importation permit or shipment labels for individual shipments.

A field set booklet, the AD-941-1 (essentially Section I of the AD-941), is available for use in the field by foreign explorers; one copy of the AD-941-1 form should accompany each shipment sent to quarantine facilities. In cases where shipments are received without AD-941 type documentation, the receiving Quarantine Facility will be responsible for completion of Section I of the AD-941 form with information to be obtained from the shipper or other sources.

Collectors and shippers must retain properly prepared specimens of the natural enemies shipped and of their field and laboratory host plants, to serve as voucher specimens. Collectors and shippers should provide receiving quarantine facilities and the BCDC with information regarding the identity of the natural enemy shipped and/or its host plant from which collected that may in time differ from that given originally on the AD-941 form. See Section V.E of these Guidelines for more information concerning voucher specimens.

V. Quarantine (Containment) Facilities, Personnel, and Operational Procedures.

All ARS facilities charged with responsibility for the quarantine receipt and clearance in the United States of foreign arthropod and nematode biological control agents for weeds must conform to certain required physical qualifications. [NOTE: THE FOLLOWING STATEMENTS ARE RETAINED PENDING DECISIONS BY ARS AND APHIS.] The facility must operate under a Compliance Agreement or Memorandum of Agreement between ARS, APHIS-PPQ, pertinent State quarantine regulatory agencies, and appropriate non-governmental institutions, e.g., universities. The Compliance Agreement, which will be monitored by APHIS-PPQ, will stipulate certain operational and documentation procedures required for operation of the facility in the quarantine receipt and handling, and transshipment and field release, of foreign arthropod and nematode biological control agents for weeds. [CLOSE OF STATEMENTS]

A. Type of Facilities Required for Quarantine Receipt of Foreign Arthropod and/or Nematode Biological Control Agents for Weeds.

All ARS facilities to be engaged in quarantine receipt of foreign arthropod and nematode biological control agents for weeds are required to be inspected and approved for such purposes by authorized representatives of APHIS-PPQ prior to approval for operation. The inspection will be conducted to insure that adequate physical safeguards exist to minimize or eliminate the possibility of escape of arthropods and nematodes from the Quarantine Facility.

General physical safeguards should include:

- 1) A double-door anteroom entryway with doors of arthropod escape-proof design (with gaskets to form a seal at all door edges, frame, and floor), and both equipped with automatic closers or electrical interlocking devices; first door locked at all times.
- 2) A warning sign outside of first entry door stating e.g., "Quarantine Area-Only Authorized Personnel Permitted Entry."
- 3) Sealed or otherwise arthropod- and rodent-proof floors, walls, ceilings, windows and doors; all pipes, conduits, etc., penetrating ceiling, walls, or floors, must be carefully sealed with silicon caulking at both inside and outside surfaces; in anteroom, use black paint for walls, doors, and ceilings; for walls in rest of quarantine use white, epoxy paint, gray for floors; windows, if any, must be triple-glazed and shatter proof.
- 4) Sealed or otherwise insect- and mite-proof electrical system, including sealed floor and wall plugs, switches and lights.
- 5) Heating, cooling, and exhaust systems, preferably closed air systems, fitted with filters adequate to prevent escape of insects and mites. A pressurized air system, with positive pressure in noncontainment areas and negative pressures in containment areas, is desirable.
- 6) Plumbing system designed to prevent escape of insects, mites, other arthropods, and nematodes, including adequate screening of floor drains and other accessible drain lines. A trap where waste water from the Quarantine Facility can be sterilized or otherwise treated is highly desirable.
- 7) Direct access in quarantine to incineration or heat treatment systems for destruction or sterilization purposes.
- 8) Traps effective for various arthropod species placed in anterooms and any other strategic possible escape routes.
- 9) Provision for maximum security area for initial opening of incoming packages of exotic material.
- 10) Provision for special confinement of individual arthropod and nematode species to separate cages, chambers, or containers within the quarantine area.
- 11) Means of providing limited access to quarantine area only to workers directly assigned to quarantine program (see also 1 above).
- 12) Intercommunication system to allow communication with quarantine personnel without need to enter or leave quarantine area.
- 13) Provision for shower room and/or for change of clothing in quarantine area; the former may be considered optional.
- 14) Sealed emergency door with panic hardware, wired to an alarm, with sign "Emergency Exit Only;" fire warning alarms in quarantine.

Special requirements for plant-feeding arthropods include:

- 1) One or more quarantine greenhouse bays for the conduct of host specificity and other biological studies; each bay must have separate air handlers, appropriate filters, concrete floors and foundations, air tightness, safety glass, hail damage protection, negative pressure, and a sterilizer.
- 2) Provision for fumigation of plant materials entering quarantine areas; preferably a pass-through autoclave, with interlocking doors that prevent inner and outer doors opening at same time.

Special requirements for plant-feeding nematodes include:

[THESE REQUIRE INPUT OF A SCIENTIFIC PANEL OF PERTINENT NEMATOLOGISTS; REQUIREMENTS MAY INCLUDE POSSIBLE NEED FOR DRAINAGE TRAPS, SETTLING TANKS, TREATMENT OF SOLID WASTES, ETC.]

For additional information on Quarantine Facility requirements and design, see Section 3 - "Quarantine Facilities" in Leppla and Ashley (1978).

B. Approval of Quarantine Facilities.

1. Inspection and APHIS Approval.

If physical safeguards are deemed to be adequate after inspection by APHIS-PPQ, or following the rectification of any deficiencies found during inspection, APHIS-PPQ will issue a dated and renewable certificate indicating approval for quarantine operation. This certificate should be prominently displayed by the approved Quarantine Facility. APHIS officials will conduct annual and unannounced re-inspections of the facility to assure the continuing adequacy of these physical safeguards. State regulatory officials are also authorized to inspect the facilities upon their request.

ARS and other facilities currently authorized to serve as quarantine facilities for arthropod and nematode natural enemies of weeds are listed in Attachment 4. No other ARS facilities are authorized to receive arthropod or nematode natural enemies of weeds directly from foreign sources, with some exceptions as authorized by APHIS-PPQ (see Section IV.C.2, and Attachment 6).

The approved ARS quarantine facilities will provide address labels and pertinent shipping instructions, including instructions to airline, post office, and customs officials as appropriate, to ARS and other overseas laboratories and personnel upon request, or to the permittee (applicant) upon notification of issuance of a permit for shipment to be received at those facilities (see Section IV.C.1).

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY ARS AND APHIS.]

2. Compliance Agreements or Memoranda of Agreement.

As noted in these Guidelines, ARS quarantine facilities will be required to operate under a Compliance Agreement or Memorandum of Agreement between ARS, APHIS-PPQ, pertinent State quarantine regulatory agencies, and appropriate non-governmental institutions, e.g., universities. The specific provisions of these Compliance Agreements or Memoranda of Agreement authorizing Quarantine Facility operations, which will vary depending on the location and type of each facility, will be determined by

APHIS-PPQ in consultation with pertinent State regulatory officials and ARS line and staff officials and research personnel. These provisions will include:

a) Approval of the physical safeguards of the Quarantine Facility, as discussed in Section V.A. above.

b) Agreement for Quarantine Facility adherence to quarantine importation permit procedures as outlined in Section IV.C of these Guidelines (insofar as Quarantine Facility involvement in such procedures is concerned), and for adherence to transshipment and release procedures as may be agreed upon, as outlined in Sections VI.A and C of these Guidelines.

c) Approval of specific quarantine operational procedures for the Quarantine Facility; as summarized in Section V.C.2 of these Guidelines, including safety considerations and precautions to be made in quarantine handling and clearance for release from quarantine of foreign arthropods and nematodes for weed control as discussed in Section VI of these Guidelines.

d) Agreement for Quarantine Facility compliance with documentation procedures to be agreed upon, as outlined in Sections IV.E, V.D, and VI.C-D of these Guidelines.

e) Any other specific procedures or regulations to be followed, or specific restrictions on types of materials to be received or shipped, as may be required by regulatory agencies of the State in which the Quarantine Facility is located.

f) Designation of specific Quarantine Officer for the Quarantine Facility responsible for assuring compliance as noted in items 2-5-above.

These Compliance Agreements or Memoranda of Agreement must be approved by the appropriate ARS and APHIS-PPQ officials, and the pertinent State regulatory agency, and will be monitored by APHIS-PPQ officials to the extent they may deem necessary. State regulatory officials are also authorized involvement in monitoring of these agreements.

[END OF SECTION]

C. Quarantine Personnel and Operational Procedures.

1. Quarantine Personnel.

Each Quarantine Facility will have a designated Quarantine Officer. Quarantine Officers will be appointed by the appropriate ARS official after consultation with the NPS, Research Leaders or Laboratory Chiefs, and Area or Center Directors. Quarantine Officers have a great deal of responsibility, and must exercise their duties at a high level of excellence. Errors in judgement potentially could have serious consequences for U.S. agriculture. The traits and attitudes of a good Quarantine Officer have been described by Fisher (1964). The Quarantine Officer will be thoroughly trained in arthropod classification and morphology, basic nematology, quarantine philosophy, and quarantine operational procedures. New Quarantine Officers should undergo apprenticeship training which allows for hands-on work under the supervision of an experienced Quarantine Officer. The Quarantine Officer is responsible for assuring that applicable quarantine procedures are followed. Specific responsibilities include assurance that there is:

a) Adherence to permit, documentation, voucher, and other specifically required procedures;

b) Proper confinement of all organisms in the quarantine areas;

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- c) Handling of these organisms, alone or by coworkers assigned to the quarantine program, is in a manner to prevent escape of organisms;
- d) Authoritative identifications of the organisms are obtained;
- e) The consignment/release of organisms from quarantine is permitted only after screening and necessary authorizations have been obtained; and
- f) Packaging and shipment of organisms is in such a manner as to prevent their escape during any further interstate transport.

Ultimate responsibility for the consignment/release of organisms from the Quarantine Facility rests with the Research Leader of the facility, who in certain cases may be designated Quarantine Officer.

Other personnel assigned to the quarantine program, including the research scientists conducting studies on the quarantined organisms, will be limited in number, and thoroughly instructed in the quarantine operational procedures (QOP) of the facility. A list of personnel authorized access to the quarantine areas will be prepared and prominently posted. All other personnel will be denied access to the quarantine areas unless accompanied by the Quarantine Officer or his designated representative.

2. Quarantine Operational Procedures (QOP)

In order to minimize the risks associated with the introduction of exotic organisms, it is important that quarantine personnel not only be highly skilled and well trained, but that they follow well defined standard operating procedures to prevent unwanted introductions.

Each ARS Quarantine Facility will prepare specialized quarantine operational procedures, which may differ depending on the location, primary mission, physical construction, and staffing of the facility. These operational procedures will be approved by appropriate ARS line and staff officials, and by APHIS and State regulatory officials prior to authorizing operation of the facility as a Quarantine Facility for receipt of foreign arthropod and/or nematode biological control agents for weeds, whichever may be the case. The approved QOP will be posted near the entrance of the quarantine area of the facility. APHIS officials will conduct periodic unannounced inspections of the facility to ascertain that these procedures are being followed, and State regulatory officials may also conduct such inspections.

Quarantine operational procedures must include reference to the following five categories:

- a. Specific permit and approval procedures for the facility.

1) Description of the permit and approval procedures for importations (see Sections IV.C) specific to the facility, to include provision for handling unsolicited shipments arriving without proper permits or approvals, and for following other specific procedures as may be stipulated by local regulatory officials.

2) Provisions for assuring maintenance of quarantine conditions for the facility, including limited access to quarantine areas, requirements for protective clothing, in order to retain authority for continued direct receipt of foreign material.

- b. Provisions for receipt, examination, and processing of incoming shipments, to include:.

1) Provision for opening of incoming shipments only in special containment areas within quarantine.

2) Procedures for dealing with packages that include potentially useful organisms or needed host material not covered by the permit; APHIS-PPQ must be notified immediately for possible post-shipment approval, which may involve contacting the TAGIBCAW.

3) Description of means for quarantine screening of imported material and for elimination of inadvertently, inappropriately, or necessarily included organisms such as soil, host plant material, extraneous invertebrates, parasites, or plant or insect pathogens.

For arthropods, elimination of any parasites will involve holding in quarantine all material received as immature stages and/or in host plants until adults emerge, and the meticulous separation of emerging species for identification. Such separation is also required when adults are received in quarantine. In certain cases, rearing of arthropods in quarantine to at least an F₁ laboratory generation may be deemed desirable to eliminate any parasites/parasitoids prior to testing, or consignment from quarantine, if field release clearance has been obtained. A final check for pathogens requires sacrifice of some of the material received; 5-10% of the agents received is suggested, if possible. If any concerns about disease remain or if the pathogen check is positive, the colony should either be destroyed or the agent must remain in quarantine and attempts be made to rear subsequent generations which are as free of disease as may be possible or warranted.

For nematodes, [REVIEW OF SAFETY REQUIREMENTS BY SCIENTIFIC PANEL OF PERTINENT NEMATOLOGISTS IS NEEDED HERE] (see also Section V.A).

In all cases, all foreign plant, extraneous arthropod or nematode, and other host or habitat (e.g., soil) material must be destroyed in quarantine as soon as possible after receipt; the QOP must indicate specific means of such destruction. Only domestic host and other materials (e.g., soil) will be used to culture natural enemies in quarantine.

- c. Notification of possible taxonomic problems and procedures for obtaining taxonomic assistance.

Means must be described in the QOP for obtaining rapid authoritative identification of arthropod and nematode species received in quarantine. Appropriate specialists should be consulted in advance for proper specimen preparation and submittal procedures. Whenever possible specimens of original parent or F₁ generation material should be submitted for identification of the initially received material. Identifications should be submitted to the appropriate taxonomic specialist for determination to the lowest possible taxon. Quarantine Officers may request advice from SEL and NL, the principal USDA centers for arthropod and nematode identifications, in establishing their facility's procedures for obtaining identifications. See Steyskal et al. (1986) for techniques for arthropod specimen preparation and Forms ARS-748 and 748A (Attachment 8) for procedures for submitting arthropod specimens to SEL for identification. See Nickle et al. (1988) for similar information concerning nematodes.

- d. General procedures for host specificity and other quarantine testing.

The QOP should include a general protocol to be followed prior to the decision to release organisms from quarantine for further shipment or field release. This protocol should include consideration of the known or tested host range and host relationships of the species or of the taxonomic group (e.g., subtribe, tribe, subfamily) to which it belongs, its potential effect on other beneficial organisms, adequacy of safeguards for elimination of parasites/parasitoids or pathogens, adequacy of taxonomic identifications, and other safety considerations listed in Section II.B of these Guidelines. The following references dealing with host-plant specificity testing are recommended reading, and some should be noted in the protocol document: Harris and Zwölfer (1968); Zwölfer and Harris (1971); Wapshere (1974, 1975, 1989); and Schroeder and Goeden (1986). The results of quarantine tests and earlier studies overseas that successfully demonstrate the safety of the foreign organism for field release in the U.S., to the satisfaction of the researcher, Quarantine Officer, and Research Leader, will be eventually presented in a petition to the TAGIBCAW for release of the organism. See also Sections IV.B and VI of these Guidelines.

- e. Other quarantine aspects to be addressed in the QOP.

- 1) Means for quarantine storage, for overwintering or other reasons, of the imported organisms.
- 2) Procedures for shipment from quarantine, including proper packaging, and permit and approval procedures (see Section VI.C of these Guidelines).
- 3) Documentation procedures (see Sections IV.E, V.D, and VI.D of these Guidelines).
- 4) Voucher procedures (see Sections V.D and VI.E of these Guidelines).
- 5) Provisions for monitoring of the QOP by the Research Leader or Laboratory Chief of the Quarantine Facility.

See Attachment 9 for an example of a brief QOP for handling plant-feeding arthropods, which includes procedures for growing noxious weeds or other prohibited plants needed for quarantine testing of the natural enemies; attention to the latter procedures needs to be made in all ARS QOPs dealing with imported natural enemies of weeds.

D. Documentation of Receipt of Imported Material.

The Quarantine Officer of each approved ARS Quarantine Facility is responsible for completion of Sections II and III of AD Form 941 (Attachment 5), which is to accompany each shipment of foreign material received (see Section III.D of these Guidelines), and for filing and distribution of the copies of this form according to instructions on the form. The Quarantine Officer is also responsible for assuring that these forms are included in all incoming shipments, or for their preparation if not so included. In cases in which the shipper has used the AD-941-1, the Quarantine Officer must complete Sections I-III of a full AD Form 941.

A record of all shipments and species received in the Quarantine Facility will be periodically provided to BCDC, APHIS-PPQ, and the pertinent State regulatory agency, as stipulated in the Compliance Agreement. (See also Section V.D for additional records to be provided by the Quarantine Facility).

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The Quarantine Officer should retain properly prepared specimens of incoming natural enemy material to serve as vouchers representing material received in quarantine; only specimens of the parent or F₁ generations should serve as actual vouchers. It is highly recommended that herbarium specimens of the original host plants (if available) and of the plants included in specificity tests also be retained as vouchers by the Quarantine Facility. See Section VI.E for additional information concerning voucher specimens, and their submittal for national collections.

VI. Quarantine Consignment, Interstate Shipment, and Field Release of Foreign Arthropod and Nematode Biological Control Agents for Weeds.

The ultimate responsibility for the release of an organism from quarantine rests with the Research Leader or Laboratory Chief of the ARS Quarantine Facility, although authority for making this decision may be delegated to a designated Quarantine Officer under certain circumstances. Procedures and considerations required prior to release from quarantine are included in the facility's QOP [FOLLOWING PHRASE IS RETAINED PENDING ARS AND APHIS DECISIONS.] and Compliance Agreement or Memorandum of Agreement approved by APHIS. The Quarantine Officer is responsible for: 1) Assurance that safety considerations and necessary tests (see Sections II.B and III) are made prior to consignment of the organism from quarantine, or that proper arrangements are made for any additional testing deemed to be required; 2) Assurance that any necessary authorizations for field release and/or interstate shipment of the organism are obtained (see Section VI.C below), which involves review of research information by TAGIBCAW, State and Federal officials, and possibly others, and APHIS-PPQ permits; 3) Documentation procedures involved following release from quarantine; and 4) Preparation of voucher specimens as appropriate.

A. Safety Considerations, Testing, and Review Procedures Prior to Application for Quarantine Consignment or Field Release.

Included in the QOP, [FOLLOWING PHRASE RETAINED PENDING ARS AND APHIS DECISIONS.] which are an integral part of the Compliance Agreement or Memorandum of Agreement to be entered into between the ARS Quarantine Facility, APHIS, and the pertinent State regulatory agency, are detailed protocols to be followed prior to release of organisms from quarantine. These protocols include in-house review and testing procedures, obtaining recommendations from the TAGIBCAW and further review as may be necessary, and application for permits from APHIS-PPQ, which involves the preparation of an Environmental Assessment for initial U.S. release of a plant-feeding organisms for biological control of weeds.

1. Quarantine Review Procedures.

No live material with insufficiently known taxonomic and host relationships will be permitted to leave quarantine. The Quarantine Officer, and/or the pertinent researcher responsible for

study of the organism, will conduct a critical review of available ecological and biological information based on the taxonomic identification of the species and discussions with relevant knowledgeable experts, including taxonomists and biological control research workers, a review of the results of studies of the organism conducted previously, and for newly imported species not yet cleared for field release will conduct the studies in quarantine as stipulated during the TAGIBCAW review procedure (see Section IV.B and Section 2 below). During these studies and later review, special attention will be made to the four areas of safety considerations listed in Section II.B of these Guidelines. Based on this review of information, tests, and discussions, conclusions are reached by the Quarantine Officer and pertinent researcher in which the identified organism is assigned to one of two quarantine clearance categories:

Class A: The organism is considered dangerous or otherwise unsuited for continued experimentation. All material placed in this category must be destroyed in quarantine.

Class D: The organism is considered safe for field release in the U.S. Material placed in this category will require additional review by the TAGIBCAW as described in Section VI.C below, prior to being consigned to non-quarantine personnel of the Quarantine Facility, field released, or shipped interstate.

2. Quarantine Testing.

Included in the four areas of safety considerations listed in Section II.B, is the need for information that may require additional testing of the organism under quarantine conditions, if such tests have not already been accomplished, or were inconclusive, during the overseas phase of the biological control program. This includes the following considerations:

a. Potential plant pests or vectors of plant pathogens. Tests are required to: (1) determine the extent of potential damage to non-target plants and potential host range of the arthropod or nematode; and (2) assure the elimination of foreign plant pathogens or their vectors. For information on host range studies, see Section IV.B above; these tests need to include provisions to ascertain whether plant species on Federal or pertinent State lists of rare or endangered species will be further endangered by the weed natural enemy proposed for introduction. If the actual tests of the organism's capability of vectoring plant pathogens are deemed necessary, they must be conducted overseas or in adequate quarantine facilities.

b. Potential animal or human pests or vectors of animal or human pathogens. Tests may occasionally be deemed desirable to determine whether the potential natural enemy is capable of causing significant harm to man or animals (vertebrate and invertebrate) and the likely extent of such action.

If, following quarantine testing of the organism, any doubt remains concerning the propriety of release of the organism from quarantine, the matter may be placed before an *ad hoc* panel of biological control specialists [PHRASE RETAINED PENDING ARS AND APHIS DECISIONS.] and/or the BCAC (see Section VI.C) for arbitration. It is important that any potential harmful effects of a natural enemy of a weed indicated by such laboratory tests be critically weighed against the potential beneficial effects of the natural enemy and the evidence obtained from field studies and published information concerning the natural enemy where it occurs in nature.

B. Field Release or Interstate Shipment of Foreign Arthropod and Nematode Biological Control Agents for Weeds.

1. General Approval and Permit Requirements.

Specific approval procedures for consignment from quarantine, field release, and/or interstate shipment of foreign arthropod and nematode biological control agents for weeds will be stated in the facility's QOP [PHRASE RETAINED PENDING ARS AND APHIS DECISIONS.] and **Compliance Agreements or Memoranda of Agreement between the involved Quarantine Facility, APHIS, and State regulatory agencies** [END OF PHRASE].

In general, these approval procedures will include:

a. A requirement for specific authorization from APHIS-PPQ for the initial field release of an exotic species in the United States, which in turn requires (1) preparation by the researcher of a document containing information for an Environmental Assessment (EA) and a review of research results on the organism proposed for release for review by the TAGIBCAW, PPQ, State regulatory agencies, **ARS, and/or BCAC**, and (2) approval of the State in which the release is intended;

b. A requirement for State approval and an APHIS permit for all interstate shipments containing these organisms;

c. Proper documentation of all quarantine consignments, shipments, and field releases from quarantine, including periodic notification of APHIS-PPQ, BCDC, and pertinent State agencies; and

d. Adequate packaging to prevent escape of organisms during transit.

The Quarantine Officer is responsible for assuring that these procedures are followed.

2. Field Release by ARS Quarantine Facilities.

a. Federal and State regulations.

Before a new candidate foreign biological control agent can be field released or shipped interstate from quarantine, provisions must be made to meet the requirements of certain Federal and State regulations impacting the introduction of exotic organisms for biological control of pests. The Federal regulations involved, in addition to the Plant Quarantine Act (PQA) and Federal Plant Pest Act (FPPA) already mentioned in these Guidelines as regulating the importation and movement of live organisms, include the following: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the National Environmental Policy Act (NEPA); and the Endangered Species Act (ESA). The ARS Research Leader, Quarantine Officer, and involved researcher, are responsible for adherence to the requirements of regulations under these Acts as noted below.

FIFRA: Under this Act, which is administered by the Environmental Protection Agency (EPA), all biological agents used for control of pests are classified as pesticides, and thus their movement and use is regulated by EPA. However, EPA has exempted from regulation under FIFRA invertebrate biological control organisms on the grounds that they are adequately regulated by the USDA, primarily by APHIS under the PQA and FPPA and associated regulations.

NEPA: Under this Act, all Federal or Federally-supported agencies must consider the environmental impact of major actions that may significantly affect the quality of the human environment in the U.S. USDA agencies interpret this to mean that, with certain exceptions, an Environmental Assessment (EA) is required for the initial field release of exotic biological control agents in the U.S. That is, an environmental risk analysis must be applied in such actions by ARS (ARS, 1986), and for the issuance of Federal permits by APHIS for the initial field release of introduced plant pests or potential plant pests. No foreign phytophagous arthropod or nematode natural enemy of weeds is exempt from this requirement, since they are all potential plant pests and can thus have detrimental effects on the quality of the environment.

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTIONS BY ARS AND APHIS.] For initial release of organisms not exempted from a formal EA requirement, environmental assessment protocols have been prepared, the complexity of which vary with the level of risk involved. Attachments 10 and 11 present formats or protocols for providing information required for developing an EA required prior to issuance of a permit for initial release of non-exempted organisms. Attachment 12 provides criteria to determine the appropriate protocol to use. [ATTACHMENT 12 NEEDS REVIEW BY SCIENTIFIC PANEL TO DETERMINE WHETHER THESE CRITERIA ARE SUFFICIENT FOR NATURAL ENEMIES OF WEEDS] In cases where the level of risk is high, an Environmental Impact Statement (EIS) will be required. See Section b below for the roles of the TAGIBCAW and BCAC in these procedures. [END OF RETAINED SECTION]

ESA: This Act, administered by the Fish and Wildlife Service (FWS) of the USDI, concerns the impact of Federal actions on native endangered and threatened animals (including arthropods) and plants in the U.S. The safety evaluations noted in Section II.B.4.b and in Section VI.A are designed to meet these concerns. Comments on these concerns and results of any test results related to them should be noted in the EA protocol document.

Several States have laws and regulations regarding environmental policy and/or endangered species within their boundaries, similar to NEPA and ESA. In addition, certain States have regulations requiring permits or approval prior to shipment or release of arthropod and nematode biological control agents within their borders, or have otherwise formally requested notification prior to such importations or releases (see Attachment 13). Knowledge of and adherence to pertinent State regulations are responsibilities of the involved ARS Quarantine Facility researcher, Research Leader, and Quarantine Officer, prior to the initial release of biological control organisms in the U.S.

- b. Procedures for obtaining authorization for initial releases of arthropod and nematode biological control agents of weeds in the United States.

Prior to initial consignment from quarantine and/or field releases of newly-imported biological control agents for weed pests in the United States, documentary evidence of the pros and cons of the proposed release, including a review of the quarantine and other research results concerning the organism proposed for release, and the views of the researcher(s), must be prepared for review by the TAGIBCAW and also possibly by the BCAC. This report or petition must be prepared by the involved research worker, and can follow roughly the format suggested by Klingman and Coulson (1982-83). An EA protocol document should also be prepared at the same time, following the short format (Attachment

10), if the organism meets the criteria shown in Attachment 12, or the long format (Attachment 11), if the organism does not meet those criteria. Both documents, or a single document combining the two formats, should be submitted to the TAGIBCAW Executive Secretary who will arrange for their review by the TAGIBCAW and by Canadian and Mexican quarantine officials; 20 copies of the document(s) are required for such reviews. The TAGIBCAW may (1) approve the proposed release with the documentation presented, (2) recommend against the proposed release, (3) request additional information and testing prior to making a decision, or (4) recommend that a detailed EA protocol document, using the long format (Attachment 11), be prepared, if not already prepared, [FOLLOWING PHRASES RETAINED PENDING DECISIONS BY ARS AND APHIS.] and that the matter be referred to the BCAC for consideration in order to obtain approval for the release. In the latter case, the researcher will prepare the detailed EA protocol document, if not already prepared, and submit it, with a copy of the report already submitted to the TAGIBCAW, to the BCAC Executive Secretary with a request for a formal review of the case. APHIS-PPQ may also request a detailed EA protocol document from the researcher and a formal review of the case by the BCAC. [END OF RETAINED SECTION]

Following a favorable recommendation by the TAGIBCAW, and/or BCAC, appropriate State approval(s) and an APHIS permit must be obtained, using PPQ Form 526, by the ARS Quarantine Facility or other facility proposing to make the initial release. Section A of PPQ Form 526 will be completed by the facility indicating the intent to field release the biological control agent in a specific State.

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY EITHER ARS OR APHIS OR BOTH.]

There are then two possible scenarios:

(1) An appropriate EA protocol document (see NEPA requirements above and Attachments 10-12), as may be amended after TAGIBCAW comments, will be prepared by the permit applicant and included with the appropriate permit application form when submitted to the State regulatory official in whose State the initial field release is intended. State approval will be indicated in Section B of the form, and the form will be forwarded by the State official to APHIS, where the document will receive an in-house review in APHIS[, and/or by BCAC as may be requested]. After a favorable review, APHIS will prepare an EA and, if this results in a Finding of No Significant Impact (FONSI), APHIS-PPQ will complete Section C of the permit application form. PPQ will return the completed form (which constitutes the permit) to the applicant, with copies to the involved Quarantine Facility (if this differs from that of the applicant), and to the BCDC and the pertinent State regulatory agency. The permits, valid for 3 years, may be renewed for another 3-year period, after which no further permits for release of the permitted organism in that State shall be required. The Quarantine Officer shall be responsible for permit renewals.

(2) For the second option, the ARS researcher proposing the initial U.S. field release of an introduced biological control agent will submit the appropriate EA protocol documents (see Attachments 10-12) to the pertinent ARS office for review. A FONSI will subsequently be prepared by ARS which will be then be included with the permit application form when sent to APHIS via the appropriate State regulatory agency. APHIS-PPQ may then issue the permit and send copies as in option 1. [END OF RETAINED SECTIONS]

The ARS Research Leader has the responsibility of giving final approval for release after APHIS and State approvals are in hand. This is done by memo to the researcher, with copies to the overseas supplier of the organism, NPS, the BCDC, the concerned Area office, and potential cooperators.

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- c. Subsequent releases of arthropod and nematode biological control agents for weeds.

Completion by the Quarantine Facility or other shipping/releasing facilities of Section A of the PPQ Form 526 for State regulatory agencies is also required for subsequent releases of the same organism in additional States. If the release is approved by the State in Section B, the PPQ Form 526 will be forwarded by the State official to APHIS-PPQ for completion of Section C. Based upon prior release approval and State recommendation, APHIS will distribute copies of the completed form (the permit) as above. The Quarantine Officer or pertinent personnel at other facilities will maintain a file of such State approvals and permits.

For certain releases in the State in which the Quarantine Facility is located of organisms already cleared for release, APHIS and State approval may be obtained on the same PPQ Form 526 used for requesting importation permits (see Section IV.C), by indicating the intent to release on the form when first submitted.

After permits are obtained for their initial releases, no other prior action is required for subsequent field release of hand-carried arthropod and nematode biological control of weeds agents in States approving their release, until expiration of the permit (generally 3 years), which must then be renewed. However, appropriate regulatory agencies in these and all other States in which releases are made shall routinely be informed periodically in writing of all releases made within their boundaries by ARS Quarantine Facility personnel. APHIS-PPQ and BCDC shall also be similarly informed. The Quarantine Officer shall be responsible for such notification.

3. Interstate Shipment from Quarantine and Non-Quarantine Facilities Engaged in Receipt or Culture of Introduced Arthropod and Nematode Biological Control Agents for Weeds.

The intended recipient of foreign arthropod and nematode biological control agents for weeds to be shipped through or otherwise received from ARS quarantine facilities, or from non-quarantine facilities, shall be responsible for obtaining State approvals and APHIS-PPQ permits for such interstate shipments. However, all shippers are responsible for ascertaining and adhering to the quarantine and other requirements of the States or Territories to which material is sent. See Attachment 13 for a list of States and Territories with such regulations. State approvals and APHIS-PPQ permits, and shipment permit labels, will be obtained using PPQ Form 526 in the same manner as such approvals or permits for field release are obtained by the Quarantine Facility (see Section VI.C.2). The Quarantine Officer can assist the intended recipient in completion of Section A of the form, as may be required.

If the material is to be field released by the recipient, this intent must be clearly indicated on the PPQ form 526. [FOLLOWING SENTENCE RETAINED PENDING ARS AND/OR

APHIS DECISION.] In cases of initial U.S. releases, State or APHIS officials may elect to request an opinion from BCAC as described above; see procedures outlined in Section VI.C. [END OF SENTENCE]

If the release in the State is approved in Section B, the PPQ Form 526 will be forwarded to APHIS-PPQ by the State regulatory agency for issuance of a permit (completion of Section C of the form) and APHIS-PPQ will provide copies of the permit to the applicant, the Quarantine Facility or non-quarantine facility, BCDC, and the State regulatory agency. PPQ will also provide a supply of shipment permit labels to be placed on packages of the approved organism for shipment interstate. The Quarantine Officer or pertinent non-quarantine personnel will maintain a file of permits and shipment labels, and will be responsible for any necessary permit renewals.

Arrangements for State approvals and APHIS permits and shipment labels must be made well in advance of intended shipments, to prevent the loss of valuable live materials while awaiting approval procedures.

All foreign arthropod and nematode biological control agents shipped from ARS quarantine facilities will: a) be packaged free of extraneous material whenever possible, and packaged in sturdy containers designed to prevent escape of the organisms during transport (see Section IV.D); b) have an APHIS-PPQ shipping permit label authorizing interstate shipment affixed to the outside of the package; and c) be accompanied by shipping record forms (see Section VI.D).

No further action is required for interstate shipment or release of the permitted foreign arthropod and nematode biological control agents, other than periodic permit renewal. However, appropriate regulatory agencies in all States to which such shipments and releases have been made will routinely be informed periodically in writing of the recipients and contents of all shipments made to, and releases made in their States by ARS quarantine and pertinent non-quarantine facilities. APHIS-PPQ and BCDC shall be similarly informed. The Quarantine Officer(s) shall be responsible for maintenance of their facility's shipment records, and for notification of State and APHIS officials, for ARS quarantine facilities.

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY EITHER ARS OR APHIS OR BOTH.]

C. Interagency Biological Control Advisory Committee (BCAC).

The BCAC is an interagency advisory group proposed to be established to provide technical support and advice to APHIS, upon request: (1) in evaluating risks with specific requests for permits to import or release exotic biological control agents; and (2) in establishing criteria for appropriate evaluation of requests for permits involving biological control organisms. The BCAC will not be involved in making regulatory decisions; it will be consulted regarding proposed importations and releases, primarily in regard to environmental safety factors, in cases in which Federal or State regulatory agencies seek further scientific input to make a regulatory decision, and can serve to resolve any substantive disagreements between APHIS and applicants, or upon specific appeal by biological control research workers, etc. See Attachment 14 for an outline of procedures involving BCAC for providing APHIS with such advice, and Section V.C below for specific information in regard to field release of introduced biological control agents. All communications with BCAC should be addressed to its Executive Secretary.

After final review of information concerning arthropod or nematode biological control agents, including information resulting from tests conducted in quarantine facilities, if any doubt remains as to the propriety of release of the organism from quarantine status, the question may be placed before BCAC for an informal review. This may be done by the Quarantine Officer of the facility in which the tests were conducted, or by research workers at that or other facilities who are interested in obtaining eventual clearance for such release. Documentary evidence pro and con will be accumulated for presentation to BCAC, together with an explanatory memo stating the position of the involved Quarantine Facility, and supportive or contradictory memoranda from interested research and regulatory officials. BCAC will respond with a consensus opinion indicating support or lack of support for the proposed quarantine action. If the consensus opinion is favorable, the Quarantine Facility can proceed with formal procedures for obtaining approval for field release or interstate shipment (see Section VI.C).

The advice of the BCAC may be solicited by the involved researcher, the TAGIBCAW, State regulatory offices, APHIS, or any other concerned scientist or regulatory official, at any point during the processes described in Sections IV.C and VI.C of these Guidelines involving the importation, clearance for consignment from quarantine, field release, or interstate shipment of foreign biological control agents for weeds. The BCAC provides a review of such proposals that is supplementary to that provided by the TAGIBCAW, and, because of the makeup of the Committee, can be better focused specifically on the biological and environmental aspects of the proposals than the TAGIBCAW.

[END OF SECTION RETAINED PENDING ACTION BY ARS AND APHIS]

D. Documentation of Quarantine Consignments, and Quarantine and Non-Quarantine Shipments and Field Releases of Introduced Arthropod and Nematode Biological Control Agents for Weeds.

Because classical biological control of weeds projects involve the introduction, release, and establishment of organisms from other countries, it is important that importations and releases be properly documented, so that pertinent information on the origin and release of the imported organisms can be made available to other biological control researchers, ecologists, taxonomists, or Federal and State regulatory officials. Sometimes, imported natural enemies are not found to be established in the U.S. until a number of years have passed following the release(s), so records must be maintained on a long-term basis.

All consignments, shipments, and releases made by ARS quarantine facilities will be documented by completion of AD Form 942 (Attachment 15), in accordance with instructions on the form. Section I of the form is to be completed by the Quarantine Officer, Section II, and Section III if appropriate, by the recipient of the material.

Material cleared for release from quarantine in accordance with procedures outlined in Section VI.A above may be consigned to non-quarantine status for further study, culture, or field release by quarantine or non-quarantine personnel of the Quarantine Facility or of other facilities. In cases of several consignments of material from the same incoming shipment or quarantine culture, a single AD Form 942 may be used to record the consignments, noting a range of consignment, receipt, and/or release dates in Sections I-III of the form. Further shipments or releases from non-quarantine cultures established from these quarantine consignments will be documented by use of the AD Form 943; see below.

Each shipment from ARS quarantine facilities shall be accompanied by an AD Form 942, with Section I completed. This form provides source, culture, and other information for the recipient of the shipment, and feedback information for the shipper on the results of the shipment. The recipient of the shipment must complete Sections II and III as applicable, and return the specified number of copies to the Quarantine Facility.

In cases where the foreign arthropod or nematode biological control agents shipped are not all immediately field released, but instead some or all are laboratory cultured for later field release, the ARS person or facility culturing the foreign species is responsible for documentation of all subsequent releases or shipments of that species until the culture is lost or discontinued. In cases in which interstate shipments are made of this cultured material, see Section VI.C.3 above; documentation of those shipments by the culturing facility is also required. The AD Form 943 (Attachment 16) is available for use to provide recipients of shipments with source and culture information and shippers with feedback information from the recipients and for documentation of non-quarantine shipments and releases. However, this form need not be used, if a similarly detailed system of providing information and documenting shipments and releases of exotic biological control agents for weeds is used and pertinent reports are made available to BCDC.

All ARS quarantine facilities, and BCDC, will be provided with supplies of AD Forms 942 and 943, and will provide, upon request, supplies of these forms to persons and facilities engaged in non-quarantine culture, shipment, release, and recolonization activities.

The Quarantine Officer of each ARS Quarantine Facility shall be responsible for assuring proper documentation of consignments, shipments, and/or releases of foreign biological control of weeds agents, using AD Forms 942 and 943 as appropriate, and for distribution of the copies of the forms, in accordance with instructions on the forms.

Periodic reports of quarantine and non-quarantine shipment and release activities may be required of the pertinent facilities by PPQ and/or State regulatory agencies.

Because of the possibility that recoveries of natural enemies may not materialize until several years after releases have been made, it is suggested that a computerized database similar to that proposed by Dysart (1981) be used by ARS quarantine facilities to permit rapid searches for information on organisms that have been received in quarantine. This is most certainly a necessity for quarantine facilities with a high volume of shipments, 50 or more per year. Copies of all importation, consignment, and release forms (AD Forms 941 and 942) should be provided by the quarantine facility to the BCDC so that the data can be entered into the national Releases of Beneficial Organisms in the United States and Territories (ROBO) database; see Knutson et al. (1987), and Coulson et al. (1988).

Documentation also includes publication of the research results of the biological control project. This includes studies on the biology and host specificity of the agents (even if found not to be suitable for field release), data on the field release, establishment, and efficacy of agents released, and any pertinent taxonomic papers, to include information on locations of voucher specimens.

E. Voucher Specimens.

Retention of specimens representing imported and released material is required in some cases, and is highly recommended in all cases, in order that vouchers relating to the importation and release of exotic organisms in the United States will be available for immediate or future study by taxonomists and biological control researchers. Voucher specimens are needed particularly to document field release of exotic organisms and to permit *ex post facto* comparisons with later field-collected material to facilitate verification of establishments in the U.S.

Of particular importance are voucher specimens to document:

- 1) The first field release in the United States of a foreign arthropod or nematode biological control agent by quarantine or other facilities; these voucher specimens should include specimens from each major geographical area (at least from each country) of origin of the released material.
- 2) Subsequent field releases of the same species from new major geographical areas.
- 3) Field releases from long-established laboratory cultures; such cultures should be periodically sampled and specimens vouchered to verify that cultures have retained their integrity.

ARS Quarantine Officers are responsible for obtaining representative specimens documenting the various actions noted above, for their proper preparation and labeling, and for their curation at the Quarantine Facility.

[THE FOLLOWING SECTIONS ARE RETAINED PENDING DECISIONS BY ARS.]

As noted in Attachment 17, the Quarantine Officer shall send certain properly prepared arthropod specimens to BCDC for inclusion in the proposed national voucher collection. Properly prepared nematode specimens should be sent to the Nematology Laboratory (NL), ARS, Beltsville, MD. The Quarantine Officer shall send with the specimens information on the origin and field release of the material represented by those specimens, and on their taxonomic identity and the name of the person making this determination; this information can be provided in the form of a reference to the file number of the pertinent shipment record form (AD-942 or -943) recording the release (see Section VI.D).

BCDC and NL will be responsible for providing the specimens with distinctive Voucher Specimen labels, with the information as noted above, and some of the arthropod specimens will be sent for deposit in the National Collection of Insects of the U.S. National Museum of Natural History, Washington, DC; others will be sent for deposit in the Canadian National Collection, Ottawa, Ontario, on a reciprocal basis. The remaining arthropod Voucher Specimens will be retained by BCDC for inclusion in the proposed U.S. National Voucher Collection for Introduced Beneficial Arthropods (see Attachment 17). Nematode Voucher Specimens will be retained in the NL nematode collection. See Steyskal et al. (1986) and Nickle et al. (1988) for information on preparation of arthropod and nematode specimens, respectively.

Additional voucher material representing newly imported or newly cultured natural enemy material may be required from time to time. It is recommended that all quarantine facilities and facilities engaged in culture activities retain properly prepared and labeled specimens documenting all importations, releases, cultures, or recoveries, as described for arthropods in Attachment 17, for reference purposes. It is also highly recommended that quarantine facilities retain properly prepared and labeled herbarium specimens representing original host plants and the plants included in the specificity tests, other than the common cultivated crop plants. [END OF RETAINED SECTION]

VII. Interstate Shipment of Native or Naturalized Arthropod and Nematode Biological Control Agents for Weeds.

All ARS facilities and personnel engaged in the field-collection or laboratory culture of native or naturalized arthropod or nematode biological control agents for shipment to other States or U.S. Territories shall be responsible for ascertaining and adherence to quarantine and other requirements of the States or Territories to which the material is to be sent (see Attachments 4 and 13). State or Territorial approvals or APHIS-PPQ permits and shipment labels are required for such shipments. These approvals or permits shall be obtained by the intended recipients in the same manner as indicated in Section V.C.3 of these Guidelines.

All ARS facilities engaged in recolonization of established foreign (i.e., "naturalized") arthropod or nematode natural enemies of weeds, or interstate shipment of laboratory cultured or field-collected native or naturalized arthropod or nematode biological control agents for weeds, will maintain a record of such recolonizations and shipments, including records of origin, dates of recolonization, dates of shipment, and shipment recipients, and will provide such records to BCDC and APHIS-PPQ on an annual basis. State or Territorial regulatory agencies may also request annual notification of recolonizations or shipments made to facilities or personnel within their boundaries. The AD Form 943 (Attachment 16) is available for use by ARS facilities for providing information to the recipient and obtaining feedback information, and for documenting the recolonizations, shipments, and/or releases. However, this form need not be used, if a similarly detailed system of providing information and documenting shipments and releases of exotic arthropod and nematode biological control agents is used and pertinent reports are made available to BCDC and APHIS-PPQ, and State regulatory officials as may be requested.

Although no voucher specimens are required, it is recommended that all facilities engaged in recolonizations or interstate shipment of native or naturalized arthropod and nematode biological control agents maintain voucher specimens to document the recolonizations and shipments for possible future reference.

VIII. Export of Arthropod and Nematode Biological Control Agents for Weeds to Other Countries.

All ARS domestic and overseas facilities and personnel making shipments of arthropod and nematode biological control agents to foreign countries will determine whether or not quarantine regulations exist in the country to which the shipment are to be made, including any requirement for quarantine entry permits, and are responsible for adherence to those regulations, if any.

All shipments to foreign countries shall be shipped in containers designed to prevent escape of organisms. Host materials or soil will not be included in the shipments unless absolutely required, and unless specific approval for such inclusion is obtained from the foreign government. If soil is required for shipment of nematodes, the soil must be autoclaved or otherwise sterilized prior to its use for shipment.

[PARAGRAPH RETAINED PENDING DECISIONS BY ARS AND APHIS.] Although not legally required, it is highly recommended that an APHIS-PPQ shipping permit label (or equivalent ARS form to be developed) be affixed to the outside of the package near the address labels, together with the foreign permit label, if applicable. These shipping permit labels may be obtained from ARS-BCDC, who will issue the labels only after receipt of documentary evidence that all foreign quarantine regulations have been met or that there are no quarantine regulations (e.g., photocopies of permits or relevant correspondence).
[END OF RETAINED PARAGRAPH]

As a courtesy and for the information of the foreign recipient, shipment record forms (AD Form 941)(Attachment 7), with Section I completed, should accompany each shipment, with a request that Section II of the form be completed, and the form returned to the sender. The sender is responsible for distribution of copies of the form in accordance with instructions on the form.

Although no voucher specimens are required, it is highly recommended that the sender of shipments to foreign countries retain such specimens to document the contents of the shipments for possible future reference.

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Selected Organizational Abbreviations and Addresses

1. USDA-ARS NPS
United States Department of Agriculture
Agricultural Research Service
National Program Staff (Biological Control)
BARC-W, Bldg. 005, Rm. 220
Beltsville, MD 20705
(301)344-3930
2. USDA-ARS BCDC
Biological Control Documentation Center
BARC-E, Bldg. 476
Beltsville, MD 20705
(301)344-1748
3. USDA-ARS SEL
Systematic Entomology Laboratory
BARC-W, Bldg. 046
Beltsville, MD 20705
(301)344-3183
4. USDA-ARS NL
Nematology Laboratory
BARC-W, Bldg. 011A, Rm. 153
Beltsville, MD 20705
(301)344-3660
5. USDA-APHIS PPQ¹
Animal Plant Health Inspection Service
Plant Protection and Quarantine
Biological Assessment and Taxonomic Support (BATS)
Federal Bldg., Rm. 624
6505 Belcrest Rd.
Hyattsville, MD 20782
(301)436-8677

¹ PPQ office (BATS) responsible for issuance of permits for movement of live plant pests and noxious weeds, and of the Executive Secretary of the Technical Advisory Group for Introduction of Biological Control of Agents of Weeds (TAGIBCAW).

Charter of the Technical Advisory Group on Introduction of Biological Control Agents of Weeds, and List of its Organizational Members

SEE NO. 17 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

PPQ Form 526: Application and Permit to Move Live Plant Pests or Noxious Weeds

SEE NO. 1 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

List of ARS Biological Control Quarantine Facilities **Proposed to be** Approved for Initial Receipt of Foreign Arthropods and Nematodes for Biological Control of Weeds

TO BE PREPARED

List of Plant Regulatory Officials of U.S. States and Territories, Canada, and Mexico

SEE NO. 3 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Guidelines for U.S. Importation of Exotic Natural Enemies of Weeds from Canada

SEE NO. 18 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Draft Guidelines (C, page 36)

AD Form 941: Biological Shipment Record - Foreign/Overseas Source

SEE NO. 5 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Form ARS-748: Identification Request

SEE NO. 6 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

An Example of a Quarantine Operational Procedures Document
(See Guidelines Section V.C.2 for possible additional items)

Guidelines for Handling Weed-feeding Arthropods in Quarantine

Introduction

_____ is in charge of the quarantine area and any changes in procedures or questions concerning the quarantine area should be addressed to him. Staff and Research Technicians at the laboratory will be authorized entry into quarantine only after reading and familiarizing themselves with these Guidelines and agreeing to adhere to them. Designated personnel of cooperating agencies, (e.g., the Biological Control of Weeds Group of the University of California, the State Department of Agriculture, the County Agricultural Commissioner) may be authorized entry provided that they have read and follow these Procedures.

General Precautions

1. Plan your trips into the quarantine area carefully and ask yourself "Is this trip necessary?" Plan ahead so that all needed supplies and equipment are taken into quarantine with you. Minimize your entries and exits at all times.
2. Always wear your laboratory coat when in the quarantine area. Put it on when you enter and replace it in the closet when you leave.
3. When necessary, wear oversleeves while working in cages to prevent any insects from going up your sleeves. Put these on over your laboratory coat sleeves.
4. Always check yourself and your clothing to be sure you are insect-free before leaving quarantine.
5. Be certain that cages and all equipment are adapted to handle organisms of unusual size or habit (e.g., fine mesh filters to contain eriophyid mites, etc.).

Importation Procedures

Organisms may be received in quarantine for the following reasons:

1. Rearing of untested foreign collected materials for identification;
2. Identification of tested and cleared material, prior to release or shipment to a secondary facility for study;
3. Culturing tested and/or cleared weed-feeding organisms to render them free from parasites and pathogens, prior to release;
4. Completion of biological and/or host specificity tests.

A. Approval and permits: ARS Guidelines for obtaining approval and permits for the introduction of weed-feeding arthropods into quarantine have been prepared and are on file with the Quarantine Officer. These must be followed. Importation permits will be issued by APHIS following consultation with the Technical Advisory Group on Introduction of Biological Control Agents of Weeds (TAG) and concurrence by those State officials within whose jurisdiction the quarantine facility lies. These permits will be supplied to the shipper and must be affixed on the outside of each package to facilitate agricultural and customs clearance at the United

States port of entry. Approval to receive unsolicited shipments may be obtained from APHIS and State Quarantine officer, either at the time of arrival in the United States, or if the shipment is received by mail, upon arrival at the laboratory. The TAG must also be informed of such shipments.

B. Shipping Containers: All containers must be of secure design and enclosed within a cloth bag to prevent escape in the event the container is broken.

C. Receipt of Shipments:

1. All packages must be opened in quarantine, preferably in a secure cage. Certain equipment items are to be in or readily accessible BEFORE opening the package: (a) aspirator, (b) small note pad for record keeping, (c) vials for insects, (d) killing jar, (e) kit containing razor blades, scissors, forceps, brush, lead pencil, waxed pencil, etc.
2. Open packages carefully, noting condition, any breakage and/or escaped insects, and any other species of insects.
3. Collect organisms with the aspirator or in vials for examination under a binocular scope in order to check their identification.
4. All organisms NOT of the correct species should be preserved for future identification.
5. Record all living, weak, and dead insects and note on appropriate record forms (AD 941 - Section II, and/or specially prepared forms). Dead or weakened specimens should be kept for identification, if such is needed, and for pathogen check. Save adequate live and/or dead material for voucher specimens.
6. All packaging and shipping materials should be sterilized before discard.
7. Complete Sections II and III of AD Form 941 or other shipment forms as needed.

Transshipment, Holding, Culturing and Testing in Quarantine

A. Species to be Repackaged and Transshipped:

1. Follow Nos. 1 through 7 under "C" above.
2. Examine material carefully for parasites or disease. It may be necessary to hold in cages for an extended period to determine if any parasites or pathogens are present.
3. Once material is determined to be free from natural enemies, verify the identification of each specimen and place into suitable containers, such as mailing tubes, for shipment.
4. Bring containers out of quarantine and package them into larger shipping containers. All insects shipped should be in double-walled packages.
5. Make certain that APHIS-PPQ permits have been obtained for shipment of the particular organism into the pertinent State, and affix the appropriate shipping permit label to the outside of the package.
5. Complete Section I of the AD 942 shipment forms and distribute copies according to the form's instructions.

B. Holding, Culturing, and Testing in Quarantine:

1. Examine each specimen under a binocular scope to determine its identity as it is taken from the shipment receipt area.
2. Material to be reared for identification should be placed in a cage and tended until identifiable forms are obtained, and then preserved.

3. Free-living forms of organisms to be cultured or tested must be caged at all times. Plants infested with endophagous stages may be held cage-free until approaching time of emergence of the free-living stages. All material should be re-identified prior to release from quarantine. Plants used for propagation purposes should be free of all pests that may interfere with the studies.

4. Material infested with unwanted parasites or pathogens must be handled in a manner to prevent unwanted release. Appropriate procedures will be devised to assure elimination of the unwanted organisms prior to field release. [THIS COULD BE EXPANDED UPON.]

Release from Quarantine

Permission to release any foreign organisms from quarantine must be documented by the TAG, the State Quarantine Officer, and APHIS as per the ARS Guidelines.

1. A report is to be prepared, giving the pertinent facts on the species (e.g., who identified it, its history in the literature, its biology, the results of host plant testing, and why it is desirable to release this species in the field)(see article by Klingman and Coulson, 1982-83). This report will be submitted to the TAG for their comment.

2. An Environmental Assessment is also required to obtain APHIS-PPQ permits for the initial release of an organism; see ARS Guidelines.

3. Written approval from APHIS-PPQ and the State Quarantine Officer, using the PPQ Form 526, is necessary before a species may be removed from quarantine for culture or release.

4. Upon receipt of approval from the above organizations, the Project Leader shall prepare a Quarantine Release Authorization memo for the laboratory Quarantine Officer stating that approval for release has been granted.

5. After the Quarantine Officer has signed the Release Authorization, examine each specimen as it is taken out of quarantine to be certain of its identification. Hold sufficient material for voucher specimens.

6. Clean all cages with chlorox solution. All plant material, soil, and pots are to be sterilized before removal from quarantine. Leave the quarantine tidy in preparation for the next importation.

7. All insects leaving quarantine should be logged out on AD 942 forms.

Handling Plant Material

Plants considered to be noxious weeds (e.g., see California Dept. of Agric. Weed Circular No. 48 (Revised), VII-14-1967) or other prohibited plants to be used for testing or culturing imported arthropods can be grown out-of-doors provided that:

1. Permission has been received from local agricultural authorities.

2. No bloom is allowed to mature and no seeds are produced, and any other restrictions that may be imposed should be followed.

3. All pots of noxious weeds are to be marked with a red label and are to be sterilized at the end of the project.

4. Plants, soil, and pots taken into quarantine are not to be removed without being sterilized.

5. Voucher specimens should be kept in the laboratory herbarium of all plants used in tests.

Care should be taken in the quarantine area to assure that no seed or plant part of foreign origin is allowed to escape.

Seeds of noxious weeds may be sown out of quarantine and the seedlings grown in the regular greenhouse, provided that:

1. A red pot label is put on each pot or bed of soil used for noxious weeds. All red tagged containers and soil must be sterilized at completion of each project.
2. Seed of noxious weeds will be stored in envelopes with a red border.

Documentation

A. Shipments from other Laboratories: An AD Form 941 shipment and receipt form should accompany each package of specimens. Each form is to be completed in quarantine and distributed in accordance with instructions. If other type or no shipping forms accompany the shipment, an AD 941 should be completed in quarantine with the best source and shipment information available.

B. Shipments to Other Laboratories: An AD Form 942 shipment and receipt form should accompany each package of insects. Section I of the form is to be completed in quarantine and Sections II and III are to be filled out and the forms distributed by the receiver in accordance with instructions.

C. Field Releases Made by Personnel of the Quarantine Facility: Complete the AD 942 shipment and receipt forms at the time of each release of organisms from quarantine and distribute them in accordance with their instructions and the ARS Guidelines. For release or shipment of non-quarantine material, the AD Form 943 should be used.

D. Quarantine Release Authorization: This is a within-laboratory memo designed to provide a written record of the Quarantine Officer's approval for removing a species from quarantine. The document indicating approval from the TAG, a copy of the Environmental Assessment, and a copy of the appropriate APHIS permit(s) should be attached to this memo. Make copies of all documents in triplicate and file with the Laboratory Secretary, Quarantine Officer, and the Project Leader.

Proposed Abbreviated Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Exotic Invertebrate Biological Control Agents of Arthropod Pests: Short Format

SEE NO. 10 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

[THIS DOCUMENT NEEDS REVIEW BY PANEL OF BIOLOGICAL CONTROL OF WEEDS SCIENTISTS AND NEMATOLOGISTS]

Proposed Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Biological Control Agents: Long Format

SEE NO. 11 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

**Proposed Criteria for Biological Control Agents for Weeds
Requiring Only an Abbreviated Protocol Document
for Providing Environmental Assessment Information
for Initial Field Releases in the United States
(Short Format)**

1. Candidate species is not in an exempted or excluded taxon, but the systematics of the species is well known, and there is significant understanding of the basic biology, behavior, ecology, and particularly the host range of the species.
2. There is no "conflict of interest" involved with the weed species against which the release of the candidate species is intended.
3. Candidate species is monophagous, and does not attack or is not harmful to any other economically or ecologically important plant species.
4. Candidate species does not attack plants in genera containing endangered species.
5. Candidate species does not "bite" or "sting" humans or domestic animals.
6. Candidate species does not attack or otherwise have a significant detrimental impact on honeybees or other important pollinators.
7. Candidate species belongs to a taxon that has been historically used successfully in previous biological control introduction programs.

NOTE: The information provided to the TAGIBCAW should accompany data presented with the "short form" protocol document for biological weed control agents.

[THESE CRITERIA NEED CAREFUL REVIEW BY PANEL OF BIOLOGICAL CONTROL OF WEEDS SCIENTISTS AND NEMATOLOGISTS]

List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries

SEE NO. 13 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES
TO BE PREPARED

Proposed Structure and Procedures of the Proposed Biological Control Advisory Committee (BCAC)

SEE NO. 7 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

AD Form 942: Biological Shipment Record - Quarantine Facility

SEE NO. 14 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

AD Form 943: Biological Shipment Record - Non-Quarantine

SEE NO. 15 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Structure and Procedures of the U.S. National Voucher Collection for Introduced Beneficial Arthropods

SEE NO. 16 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Draft Guidelines (C, page 44)

**Proposed ARS Guidelines for the
Importation, Interstate Movement, and Field Release in the United States of
Foreign Microbial Pathogens (Fungi, Bacteria, Rickettsia, Viruses, Protozoa)
for Biological Control of Arthropod Pests of Plants, Humans, and Animals,
and Vectors of Plant, Human, and Animal Pathogens,
and for the Interstate Movement and Export of Foreign and Native
Arthropod Pathogens for Research¹**

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Attachments

1. PPQ Form 526: Application and Permit to Move Live Plant Pests or Noxious Weeds
2. **Proposed** PPQ/ARS Form __: Application and Permit to Move Living Beneficial Organisms
3. List of Plant Regulatory Officials of U.S. States and Territories
4. VS Form 16-3: Application for Permit to Import or Transport Organisms or Vectors
5. **Proposed** AD Form 944: Record of Shipment of Exotic Microorganisms for Biological Control
6. List of ARS Biological Control Facilities **Proposed to be** Approved for Initial Receipt of Foreign Microbial Biological Control Agents for Arthropod Pests
7. **Proposed** List of Microbial Biological Control Agents for Arthropod Pests Exempted from the Requirement of a Formal Environmental Assessment
8. **Proposed** Criteria for Exemption of Microbial Biological Control Agents for Arthropod Pests from the Requirement of a Formal Environmental Assessment for Field Release
9. **Proposed** Abbreviated Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Exotic Microbial Biological Control Agents of Arthropods: Short Format
10. **Proposed** Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Exotic Microbial Biological Control Agents of Arthropods: Long Format
11. **Proposed** Criteria for Microbial Biological Control Agents of Arthropods Requiring Only an Abbreviated Protocol Document for Providing Information for an Environmental Assessment (Short Format)
12. List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries
13. Structure and Procedures of the **Proposed** Biological Control Advisory Committee (BCAC)
14. **Proposed** AD Form 944A: Documentation of Release of Exotic Microorganisms for Biological Control
15. **Proposed** ARS Repositories for Cultures of Microbial Biological Control Agents for Arthropods in the United States

¹ Original draft prepared by J. R. Coulson from 1978 draft material by A. M. Heimpel (ARS); revisions by R. A. Humber and J. R. Coulson (ARS), from comments provided by J. V. Maddox (University of Illinois), C. W. McCoy (University of Florida), and T. J. Poprawski and J. L. Vaughn (ARS), and following review by Working Session participants (see Appendix 1) in January, 1991.

I. Intent and Scope of these Guidelines.

These Guidelines are intended to provide detailed procedures required for the importation, interstate shipment, and field release of foreign pathogens of arthropods for diagnosis and laboratory research, and for biological control research and development programs involving field release of the foreign microbials in the United States. These procedures are designed to insure that every reasonable precaution will be taken to contain and prevent the escape or release of organisms that are injurious to agricultural, horticultural or forestry commodities, humans and domestic animals, or other beneficial arthropods, or that are otherwise detrimental to the environment.

Organisms for which these Guidelines are intended include all foreign species, strains, or pathotypes of fungi, bacteria, protozoa, viruses, rickettsias, and mycoplasmas (including spiroplasmas) that are imported for study or utilization as pathogens in the biological suppression of arthropod pests of plants, livestock, and humans, and for imported host arthropods infected with these organisms. Separate Guidelines exist for the importation and release of insect-parasitic nematodes, plant pathogens for control of weeds, microbial and other organisms for control of plant nematodes and plant pathogens, and invertebrates for biological control of arthropods and weeds.

These Guidelines also include procedures for the export of foreign or domestic microbial pathogens of arthropods to other countries for research on biological control of arthropod pests.

Field testing, development, and utilization of microbial pathogens of domestic origin in the United States, research leading to the development of potential microbial pesticide products utilizing either foreign or native organisms, and research on genetic engineering of organisms will be guided by separate authority and guidelines.

Some organizational abbreviations used in these Guidelines are:

APHIS - Animal and Plant Health Inspection Service, USDA
ARS - Agricultural Research Service, USDA
BCAC - Interagency Biological Control Advisory Committee Proposed
BCDC - Biological Control Documentation Center, ARS
BCIRL - Biological Control of Insects Research Laboratory, ARS
CDC - Centers for Disease Control, USDHHS
EPA - Environmental Protection Agency
FDA - Food and Drug Administration
IBL - Insect Biocontrol Laboratory, ARS
PHS - Public Health Service, USDHHS
PPQ - Plant Protection and Quarantine, APHIS
PPRU - Plant Protection Research Unit, ARS
SEL - Systematic Entomology Laboratory, ARS
USDA - United States Department of Agriculture
USDHHS - United States Department of Health and Human Services
VS - Veterinary Services, APHIS

Draft Guidelines (D, page 4)

II. Summary of Procedural Policies and General Safety Considerations.

A. Summary of Procedures for Importation, Interstate Shipment, Field Release, and Export of Microbial Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests.

The Plant Quarantine Act of 1912 and the Federal Plant Pest Act of 1957 prohibit the importation and movement of pathogens, vectors, and articles that might harbor these organisms, unless authorized by the U.S. Department of Agriculture (USDA). The National Environmental Policy Act of 1969 (NEPA) contains provisions that impact upon the release of exotic organisms into the environment. Regulations under these Acts are enforced by the Plant Protection and Quarantine Programs (PPQ) and Veterinary Services (VS) of the Animal and Plant Health Inspection Service of the USDA. The importation and shipment of pathogens and vectors of pathogens of humans are regulated by the Public Health Service (PHS), USDHHS; if such importations or movements are contemplated by ARS facilities, information on these regulations can be obtained from the Foreign Quarantine Program, Centers for Disease Control, PHS, USDHHS, Atlanta, GA 30333, or PHS Quarantine Stations at U.S. ports of entry.

The Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (FIFRA), as amended, authorizes the Environmental Protection Agency (EPA) to provide regulations concerning the development, movement, and use of pesticides, which by definition includes the development and utilization of microbial pesticide products. ARS scientists are required to have knowledge of and adhere to those EPA regulations in development of pesticide products involving microbial organisms of both foreign and domestic origin. EPA guidelines for microbial pesticides appear in 40 CFR Part 158 Subdivision M, Part A "Microbial Pest Control Agents." Note: Those guidelines do not cover importation or interstate movement of agents.

The determination of the adequacy of quarantine or containment facilities for receipt and laboratory testing of foreign organisms, and of the technical competence of investigators, is the responsibility of APHIS (PPQ and VS), and pertinent State Departments of Agriculture, and PHS in the case of importation of vectors of human pathogens. Determining the requirements that must be met for introduction of such organisms into containment and into the field is also their responsibility. [NOTE: THE FOLLOWING STATEMENT CONTAINS A PROPOSAL AND IS RETAINED PENDING ACTION BY ARS, APHIS AND OTHER AGENCIES.] In the case of foreign beneficial organisms for biological control, an interagency Biological Control Advisory Committee (BCAC) has been (proposed to be) established to provide technical support and advice to APHIS (and the PHS as may be required) and researchers, upon request, on proposed importations and releases of foreign biological control agents in the United States. [CLOSE OF STATEMENT] APHIS, PHS, and BCAC want to assure that safety considerations such as those listed below are made prior to importation or field release of foreign biological control organisms in the United States.

Certain of the below listed safety considerations can be made before importation of the proposed biological control agent, while others can be made during the domestic containment phase of the introduction program. The procedures detailed in these Guidelines are designed to assure that such considerations are made and necessary precautions are taken.

The following references are recommended for study in conjunction with these Guidelines: Poinar and Thomas (1984); Lima (1983); Richardson and Barkley (1984); Coulson and Soper (1989);

Howarth (1991); and Maddox (1991).

The more important conditions required for the importation and release of foreign microbial pathogens for control of arthropod pests as reflected in these Guidelines can be summarized as follows:

- 1) All foreign organisms shipped to the United States or later shipped interstate must be shipped in containers meeting USDA standards, and must be shipped with APHIS (and as necessary PHS) approval. See Sections III.A-B and V.B.
- 2) Foreign microbials for biological control, with few exceptions, must be received, with proper documentation, in facilities approved by APHIS (and PHS as necessary), where at least preliminary examination will be made and all contaminants and other materials deemed to be of potential hazard or detriment are to be destroyed, and where the foreign material will be stored or all or portions re-routed to other competent and approved laboratories will be made, as may be deemed necessary or desirable. See Sections III and IV.
- 3) Importation of pathogens in living host arthropods is permitted only when necessary (e.g., for diagnostic purposes), and such importations shall be made through an appropriate arthropod quarantine facility. See Sections III.A and IV.
- 4) Appropriate identifications of the foreign organisms are required prior to their release from containment. See Sections II.B and V.A.
- 5) All necessary testing must be conducted prior to release from containment. See Sections II.B and V.A.
- 6) Evaluation of the potential impact of the proposed release on nontarget organisms, and other safety considerations as listed below must be made prior to field release of the organism. An Environmental Assessment is generally required prior to field release of the organism. See Sections II.B and V.
- 7) Determination of "native" pathogens of the target arthropod or close relatives present in the proposed field release site is highly recommended. See Section V.C.
- 8) Voucher specimens of an appropriate sort to document the field release of exotic organisms are required, and certain other documentary procedures are to be followed, during which APHIS and other officials are to be kept informed of all releases and shipments. See Sections III.C, IV.C, and V.E-F.
- 9) For export of microbial pathogens for research purposes, adherence to quarantine requirements of the pertinent foreign countries is necessary prior to the shipment of the organisms into those countries. See Section VI.

B. Safety Considerations Required for Importation and Field Release of Foreign Microbial Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests in the United States.

The following safety considerations, discussed further throughout these Guidelines, must be evaluated prior to considering the importation or release of foreign microbial pathogens of arthropods into the United States:

1. Importation.

a. Diseased phytophagous arthropods.

The introduction of diseased material should be restricted to shipping dead infected hosts. If any live arthropods are received, they must be destroyed in containment or quarantine as soon as possible. Most entomopathogens will survive for a sufficient time if sent by air. The possible exception is bacteria and these should be cultured if there is no resistant stage such as a spore. If the bacteria are fastidious and cannot be cultured they should be shipped in freshly killed hosts.

b. Diseased biting insects and ticks - Vectors of vertebrate disease.

Diseased living and dead vectors of vertebrate disease must be confined in a Class III Biological Containment Cabinet in a quarantine or containment facility, and live arthropod material must be destroyed there as soon as possible. Any non-occluded viruses, rickettsia, mycoplasma, bacteria, or protozoa should be identified and submitted to animal testing before release from containment.

c. Fungi.

Most fungi attacking insects and mites are considered harmless for other animals except in rare cases. Fungi should be cultivated under aseptic techniques and identified. Special care should be taken with the Entomophthorales until identification is made to limit direct contact with and to prevent accidental release from containment of *Conidiobolus coronata* (formerly *Entomophthora coronata*) or other species of *Conidiobolus* or *Basidiobolus* known to cause vertebrate mycoses.

d. Bacteria.

Bacteria should be handled with strict aseptic techniques until positive identification is made. Fastidious bacteria should be propagated in susceptible insects of domestic origin that are caged or confined so that there is no possibility of escape.

e. Protozoa.

Generally, the protozoa can be handled aseptically until positively identified. The *Coccidia* should be tested by intraperitoneal injection in mice before being handled more freely. Confined honey bee tests of both *Coccidia* and *Microsporidia* should be carried out before release in the field.

f. Viruses.

There is ample evidence that the Baculoviruses (occluded) are harmless to all other life forms except the susceptible host insects. For this reason there need be no restriction upon importation of these viruses either as suspension of inclusion bodies or in the virus-killed insect.

All of the non-occluded insect viruses should be handled using strict aseptic techniques and should not be released outside of the laboratory until adequate tests of confined honey bees are made.

g. Rickettsias.

There is nothing to be gained by importing rickettsias for insect control. They have proven potentially dangerous since they grow in vertebrate cells and can cause death when injected. It is recommended that rickettsia be imported according to CDC guidelines for animal pathogens. Should an unknown dead insect be imported and be shown to have been killed by rickettsia, it is recommended that it be destroyed. Any releases from quarantine or containment should be strictly regulated according to APHIS policies and procedures.

h. Mycoplasmas (including spiroplasmas).

These organisms have been found causing disease in plants, insects, and vertebrates. Material infected with mycoplasma should be handled only in a Class III Biological Containment Cabinet until their spectrum of activity can be thoroughly understood. Strict aseptic technique should be employed at all times. Axenic cultures of Mollicutes can be handled safely in microbiological Biosafety Level 2 facilities.

2. Field Release.

Submittal to USDA and State authorities of an Environmental Assessment (EA) is generally required to receive a USDA permit for the field testing of foreign microbial organisms for biological control. In general, the environmental considerations of the EA are much the same as those called for under FIFRA's requirements for an Experimental Use Permit (EUP) for microbial pesticides. Those considerations to be documented in the EA include:

a. Protection against release of plant or vertebrate pathogens.

b. Protection against release of pathogens inimical to native or introduced beneficial arthropods, including biological control agents for arthropods and weeds, pollinators, and endangered arthropod species.

III. Initial Importation of Foreign Microbial Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests.

Research workers should obtain as much pertinent information as practical concerning foreign biological control agents proposed for importation prior to their shipment to the United States. This information should include, if possible, an identification of the organism and its host(s)/prey, and pertinent biological information based on literature reviews and field observations, to assess the potential usefulness and safety of the candidate biological control agent.

Precautions as indicated in this Section of these Guidelines are designed to provide for the safe shipment and receipt of all foreign microbial biological control agents for arthropod pests, regardless of the amount of preliminary information obtained overseas. Additional information may be required to be accumulated overseas prior to clearance of the biological control agent for release from quarantine or containment.

In connection with overseas studies and explorations, it is recommended that the following reference be studied: Weiser and Briggs (1971); and Poinar and Thomas (1984).

All potential microbial biological control agents for arthropod pests shipped to the United States from foreign sources must: 1) have appropriate APHIS shipping permit labels affixed to the outside of the packages; 2) be shipped in containers meeting certain specifications; 3) be accompanied by specified documentation; and 4) be routed to and received and opened in designated APHIS-approved facilities (see also Section IV), with certain exceptions.

Inclusion of plant or host arthropod material, or soil, in shipments from foreign sources will be limited to those cases in which such inclusion is a necessity. Should potentially useful organisms and/or host material not covered by APHIS permits or authority be received in quarantine or containment, APHIS should be notified after positive identification is made for post-shipment approval.

A. Approvals, Permits, and Shipment Labels for Importation.

1. General Procedures.

APHIS permits and permit labels are required for importation of pure cultures of entomopathogens and of diseased arthropods from foreign sources for diagnostic purposes or laboratory research. Special individually issued permits and permit labels will be required for the importation and later interstate movement for each individual shipment from foreign sources containing a) live diseased arthropod hosts or plant material; b) diseased beneficial arthropods, such as bees, pollinating insects, parasites or predators; and c) diseased arthropods affecting humans or animals, i.e., those feeding upon the blood of humans or animals or vectors of human or animal diseases. PHS permits are required for shipments of human pathogens, or organisms with a high probability of acting as human pathogens, or live vectors of such pathogens.

a. For pathogens for control of arthropod plant pests.

An APHIS permit and shipment labels for individual shipments or series of shipments of *pure cultures* of pathogens of plant pests from foreign areas shall be requested by the intended recipient or the shipper by completion of Section A of PPQ Form 526, Application to Move Living Beneficial Organisms (Attachment 1). [NOTE: THOUGH THE PPQ 526 IS THE CURRENTLY ACCEPTED FORM FOR OBTAINING APHIS-PPQ PERMITS, IT IS PROPOSED THAT A SIMILAR FORM SPECIFICALLY DESIGNED FOR BIOLOGICAL CONTROL ORGANISMS NOT DEEMED TO BE PLANT PESTS BE DEVELOPED BY PPQ (OR ARS) FOR USE BY ARS IN OBTAINING PERMITS FOR IMPORTATION AND INTERSTATE SHIPMENT OF SUCH BENEFICIAL ORGANISMS (PERHAPS FOR PURE CULTURES ONLY), IN PLACE OF THE PPQ-526; SEE ATTACHMENT 2.] Particularly important information to be included on this form are indications of any host material (plant or arthropod) to be included in the shipments, if any, the APHIS-approved facility to which the shipments are to be initially sent, and the intended final destination of the pathogen material. Arrangements must be made with the designated ARS receiving facility for receipt, handling, and transshipment well in advance of intended importations. The application (PPQ Form 526) should be sent to the regulatory official of the State in which the final destination is located, with a request that Section B of the form be completed and the form be forwarded to APHIS-PPQ. See Attachment 3 for a list of the addresses and telephone numbers of State regulatory officials.

Before PPQ acts on the permit application, they will consult with pertinent microbiologists of the receiving facilities or other organizations, and State and other regulatory officials as warranted. [NOTE: THE FOLLOWING STATEMENT IS RETAINED PENDING ACTION BY ARS, APHIS, AND OTHER AGENCIES.] At this time, the BCAC (see Section V.D) may also be consulted by PPQ. After these consultations, PPQ will either issue a permit for the importation, deny the request, or request additional information prior to making a decision. The permit consists of the completed PPQ Form 526 indicating PPQ approval and any special stipulations in Section C of the form. If importation is approved, PPQ will send the permit to the applicant, with copies to the appropriate quarantine or containment receiving facilities and State regulatory officials and to the BCDC. PPQ will also send appropriate shipment permit labels to the applicant for forwarding to the shipper. The shipment label will be placed on the outside of each shipment package, to facilitate passage of the shipment through the mails or customs. The shipment labels indicate PPQ approval of the shipment.

Permits for the receipt of *living diseased host arthropods* will stipulate initial receipt at approved arthropod quarantine facilities, where the material will be inspected to assure proper packaging, and that no live arthropods or plant material are forwarded unless special permit has been obtained. The material will then be forwarded to the ARS primary pathogen receiving facility for examination and transshipment. If regulatory officials of the receiving state and APHIS agree that the living exotic arthropods could not be a pest if accidentally released from containment at the designated pathogen receiving site, and if appropriate officials of the approved arthropod quarantine facility are confident that the live arthropods in the shipment are properly identified, the shipment including the live exotic arthropods can be sent directly to the designated pathogen receiving laboratory to be opened and confined in containment; all living arthropods will be destroyed at the earliest possible time after processing.

These permits and shipment labels are generally valid only for initial receipt of shipments of foreign material. See Sections V.B-C of these Guidelines for procedures for interstate shipments and for field release of imported pathogens. Supplies of PPQ Form 526 permit application are available from APHIS-PPQ or ARS-BCDC.

b. For pathogens for control of arthropod medical and veterinary pests.

An APHIS permit and shipment labels for individual shipments or series of shipments of *pure cultures* of pathogens of medical and veterinary pests from foreign areas shall be requested by the intended recipient or the shipper by completion of VS Form 16-3 (Attachment 4). Particularly important information to be included on this form are indications of any host material (plant or arthropod) to be included in the shipments, if any, the APHIS-approved facility to which the shipments are to be initially sent, and the intended final destination of the pathogens. Arrangements must be made with the designated receiving facility for receipt, handling, and transshipment well in advance of intended importations.

The permit application (VS Form 16-3) should be sent to VS, at the address shown on the form. Before VS acts on the permit application, they will consult with pertinent microbiologists of the receiving facility or other organizations, and State and other regulatory officials as warranted. [NOTE: THE FOLLOWING STATEMENT IS RETAINED PENDING ACTION BY ARS, APHIS, AND OTHER AGENCIES.] At this time, the BCAC (see Section V.D) may also be consulted by VS. After these consultations, VS will either issue a permit (VS Form 16-3a) for the importation, deny the request, or request additional information prior to making a decision. If importation is approved, VS will send the permit to the applicant, with copies to the appropriate quarantine or containment receiving facilities and State regulatory officials and to the BCDC. VS will also send appropriate shipment permit labels to the applicant for forwarding to the shipper. The shipment label will be placed on the outside of each shipment package to facilitate passage of the shipment through the mails or customs. The shipment labels indicate VS approval of the shipment.

Permits for the receipt of *living diseased host arthropods* will stipulate initial receipt at approved arthropod quarantine facilities, where the material will be inspected to assure proper packaging, and that no live arthropods or plant material are included unless special permit has been obtained. The material will then be forwarded to the ARS primary pathogen receiving facility for examination and transshipment. If regulatory officials at the receiving state and APHIS agree that the living exotic arthropods could not be a pest if accidentally released from containment at the designated pathogen receiving site, and if appropriate officials of the approved arthropod quarantine facility are confident that the live arthropods in the shipment are properly identified, the shipment including the live exotic arthropods can be sent directly to the designated pathogen receiving laboratory to be opened and confined in containment; all living arthropods will be destroyed at the earliest possible time after processing.

There are special requirements in cases where *potential human pathogens* are to be imported or host arthropods known to feed on human blood or to be vectors of human pathogens must be imported with their pathogens. For information about these requirements, ARS personnel must contact the Foreign Quarantine Program, Center for Disease Control, PHS, USDHHS, Atlanta, GA 30333, or PHS Quarantine Stations at U.S. ports of entry. The VS Form 16-3 may be used to apply for importation permits.

The permits and shipment labels discussed here are generally valid only for initial receipt of shipments in quarantine or containment facilities. See Sections V.B-C of these Guidelines for procedures for obtaining approvals for interstate shipments and for field release of pathogens. Supplies of VS Form 16-3 permit application are available from APHIS-VS or ARS-BCDC.

2. Special Procedures for Importation: Overseas Biological Control Laboratories and Explorations, and Specially-Designated Domestic Receiving Facilities.

APHIS and/or ARS [PENDING ACTION BY APHIS AND ARS ON NEW PERMIT APPLICATION FORM AND PROCEDURES] can issue permits and shipment labels on a blanket basis, to be reviewed and renewable every two years, to ARS and other overseas biological control laboratories or competent biological control workers otherwise conducting extensive overseas exploration or research, and to domestic locations approved for initial receipt of shipments of entomopathogens or diseased arthropods from overseas locations. Issuance of these permits and supplies of permit labels will be for shipments of pure cultures of entomopathogens or *dead*, diseased host material, without included plant material, and will be made in response to memoranda explaining in appropriate detail the purposes for which the permits and shipment labels are intended. Such memoranda shall be accompanied by PPQ Form 526 (Attachment 1), with Section A completed by the applicant. Completed application forms and explanatory memoranda will be sent to the appropriate State regulatory official (see Attachment 3) for State approval. Approved forms and memoranda will be forwarded to APHIS-PPQ by the State officials.

These shipment labels are for use for shipments only of biological control agents without live animal or any plant host material. If plant or live arthropod host material is expected to be included in the shipments, a formal permit from PPQ or VS is required, following the general procedures as discussed in Section III.A.1.

PPQ or VS will provide the BCDC and the appropriate State regulatory officials with a record of shipment labels issued, and the recipients of the labels will furnish PPQ or VS, BCDC, and State regulatory offices with a record of material imported under these special procedures on a periodic basis (see also Section V.E of these Guidelines).

3. Shipments to Other Facilities.

The requirement for initial receipt in specially approved facilities may be waived in cases of some shipments entering the United States from Canada and Mexico, and in certain other cases as determined by PPQ or VS. However, a permit for such importations is still required, which will include consultation with appropriate research and regulatory personnel (see Section III.A.1).

B. Shipping Containers for Importation.

Shipping containers will vary according to the requirements of the material to be shipped. However, in all cases, material from foreign sources must be shipped in a container within a container, both of sturdy construction and capable of being sealed. The outer container should be of sturdy impact-resistant material and be enclosed in finely-woven, securely sealed, heavy cloth or canvas, or heavy wrapping paper. The inner container may be of metal, wood, heavy glass, cardboard, or plastic, and should be securely sealed; this container may also be wrapped and sealed in paper, tightly-woven cloth, or other type sealing materials. Approved packing materials necessary for cushioning the inner package within the larger container, include absorbent cotton or processed cotton free of cottonseed, cellulose or plastic materials, excelsior, paper or paper products, sponge rubber, or vermiculite.

See Richardson and Barkley (1984) and Alexander and Brandon (1986) for other information concerning packaging of microbial organisms for shipment.

Both the inner and outer container and all packing material will be destroyed or otherwise treated by incineration, heat or other methods, after contents are removed in the receiving facility, in such a manner that any included pathogens or other organisms are destroyed. Specific procedures will be indicated in facility's Operational Procedures (see Section IV.B).

C. Documentation of Importation.

All shipments or series of shipments from foreign or overseas sources, or shipments from domestic sources that require quarantine receipt, shall be accompanied by an AD Form 944 (Attachment 5), with Section I of the form completed in accordance with instructions on the form. This proposed form provides source, culture, and other information for the recipient of the shipment, and feedback information for the shipper on the results of the shipment. All ARS and other overseas laboratories and personnel engaged in shipping microbial biological control agents to the United States, and all approved domestic ARS receiving facilities for exotic arthropod pathogens, will be provided by the BCDC with a supply of these forms, and the forms will be issued by them or by BCDC to explorers or other overseas shippers when notified by PPQ or VS of the issuance of an importation permit or shipment labels for individual shipments. In cases where shipments are received without AD-944 type documentation, the receiving facility will be responsible for completion of Section I of the AD-944 form with information to be obtained from the shipper or other sources. See also Section IV.C for further documentation activity upon shipment receipt.

Whenever possible, ARS collectors and shippers should retain properly preserved specimens of the pathogens shipped and of their hosts, to serve as voucher specimens. Collectors and shippers should provide receiving facilities and the BCDC with information regarding the identity of the pathogens shipped and/or their hosts that may in time differ from that given originally on the AD-944 form. See Section V.F of these Guidelines for more information concerning voucher specimens.

IV. Containment Facilities for Receipt of Foreign Arthropod Pathogens; Personnel and Operational Procedures.

All ARS facilities charged with responsibility for the initial receipt and clearance in the United States of foreign microbial biological control agents for arthropod plant or medical and veterinary pests must conform to certain required physical qualifications, and must operate under special permit conditions required by APHIS and pertinent State quarantine regulatory agencies. These permit conditions, which will be monitored by APHIS, will stipulate certain operational and documentation procedures required for operation of the facility in the receipt and handling, and transshipment and field release, of foreign microbial biological control agents.

A. Type of Facilities Required for Initial Receipt of Foreign Microbial Biological Control Agents for Arthropod Plant and Medical or Veterinary Pests.

All ARS facilities to be engaged in initial receipt and transshipment of foreign arthropod pathogens are required to be inspected and approved for such purposes by authorized representatives of PPQ, and VS or PHS as appropriate, prior to issuance of a importation permit authorizing such operations. The inspection will be conducted to insure that adequate physical safeguards exist to minimize or eliminate the possibility of escape of pathogens from the facility.

These physical safeguards, which will vary depending upon the type of organisms to be received, shall be of a stringency minimally equal to those described for Biosafety Level 2 for infective agents formulated by the CDC (Richardson and Barkley, 1984). Containment facilities minimally meeting the requirements for certification as Biosafety Level 2 are suitable for the receipt of naturally occurring exotic organisms; quarantine facilities minimally meeting requirements for certification as Biosafety Level 3 are required for the receipt, handling, or research involving the creation of genetically engineered microbes. The physical safeguards for receipt of naturally occurring exotic organisms shall include:

- 1) The laboratory is designed so that it can be easily cleaned.
- 2) Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- 3) Laboratory furniture is sturdy, and spaces between benches, cabinets, and equipment are accessible for cleaning.
- 4) Each laboratory contains a sink for hand washing.
- 5) If the laboratory has windows that open, they are fitted with fly screens.
- 6) An autoclave for decontaminating infectious laboratory wastes is available.
- 7) Laminar flow biological safety cabinets of Class II Type A are used whenever procedures with a high potential for creating infectious aerosols are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.

8) Optional measures in the design of the Containment Facility include the following:

a) Heating, cooling, and exhaust systems, preferably closed air systems, fitted with filters adequate to prevent escape of insects and mites. A pressurized air system, with positive pressure in non-containment areas and negative pressures in containment area, is desirable.

b) Plumbing system designed to prevent escape of insects, mites, and other arthropods, including adequate screening of floor drains and other accessible drain lines. A trap where waste water from the Containment Facility can be sterilized or otherwise treated is highly desirable.

In the special cases in which live foreign host arthropods are to be imported into the Containment Facility (see Section III.A), the "optional measures" listed above, and other physical features and precautions involved in Quarantine Facilities for receipt of arthropod parasites and predators (see pertinent Guidelines), may be required in order for a permit to be issued.

If foreign host arthropods known to be vectors of human pathogens must be imported with their pathogens, special physical facility requirements will need to be met. For information about these requirements, ARS personnel must contact the Foreign Quarantine Program, Center for Disease Control, PHS, USDHHS, Atlanta, GA 30333, or PHS Quarantine Stations at U.S. ports of entry.

Additional facilities or precautions required for certification at the Biosafety Level 3 include the following:

1) The containment laboratory is separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the containment laboratory from access corridors or other contiguous areas. Physical separation of the high containment area from access corridors or other laboratories or activities may also be provided by a double-doored clothes room (showers may be included), airlock, or other access facility which required passage through two sets of doors before entering the area.

2) The interior surfaces of walls, floors, and ceilings are water resistant so that they can be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate decontaminating the area.

3) Each laboratory contains a sink for hand washing. The sink is foot, elbow, or automatically operated and is located near the laboratory exit.

4) Windows in the laboratory are closed and sealed.

5) Access doors to the laboratory or containment module are self-closing.

6) An autoclave for decontaminating laboratory wastes is available, preferably within the containment area.

7) A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory through the entry area. The exhaust air is not recirculated to any other part of the building, is discharged to the outside, and is dispersed away from occupied areas and intakes. Personnel must verify that the direction of the airflow (into the containment area) is proper. The exhaust air from the containment area can be discharged to the outside without being filtered or otherwise treated.

8) The HEPA-filtered exhaust air from Class I or Class II biological safety cabinets is discharged directly to the outside or through the building exhaust system. Exhaust air from Class I or II biological safety cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every twelve months. If the HEPA-filtered exhaust air from Class I or II biological safety cabinets is to be discharged to the outside through the building exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or building exhaust system.

For additional information on facility requirements for receipt of and research on arthropod pathogens, see Richardson and Barkley (1984).

If physical safeguards are deemed to be adequate after inspection by PPQ, and VS or PHS as necessary, or following the rectification of any deficiencies found during inspection, and subsequent issuance of an importation permit (see Section III above), APHIS (PPQ and/or VS) will issue a dated and renewable certificate indicating approval for operation of the facility as a primary receiving center for foreign arthropod pathogens. This certificate should be prominently displayed by the approved facility. APHIS officials will conduct unannounced re-inspections of the facility to assure the continuing adequacy of these physical safeguards. State regulatory officials are also authorized to inspect the facilities upon their request.

ARS and other facilities currently proposed to be authorized to serve as initial receiving facilities for arthropod pathogens are listed in Attachment 6. No other ARS facilities are authorized to receive arthropod pathogens directly from foreign sources, with some exceptions as authorized by PPQ or VS (see Section III.A.3).

The approved ARS containment facilities will provide address labels and pertinent shipping instructions, including instructions to airline, post office, and customs officials as appropriate, to ARS and other overseas laboratories and personnel upon request, or to the permittee (applicant) upon notification of issuance of a permit for shipment to be received at those facilities (see Section III.A.1).

B. Facility Personnel and Operational Procedures.

1. Receiving Facility Personnel.

Each major ARS receiving facility for arthropod pathogens will have a designated Containment Officer. These will be appointed by the appropriate ARS official after consultation with the NPS, Research Leaders or Laboratory Chiefs, and Area or Center Directors. The Officer will be thoroughly trained in quarantine philosophy and containment operational procedures for arthropod pathogens, and will be responsible for assuring that these procedures are followed. Specific responsibilities include:

a) Maintenance of the physical safeguards of the facility as discussed in Section IV.A.

b) Adherence to permit, documentation, voucher, and other specifically required procedures or restrictions on types of materials to be received or shipped, as may be required by APHIS and the regulatory agencies of the State in which the facility is located;

c) Proper confinement of all organisms in the containment areas;

d) Handling of these organisms, by himself or any worker assigned to the quarantine program, in a manner to prevent escape of organisms;

- e) Obtaining authoritative identification of the pathogens and hosts to the extent as may be required;
- f) Authorizing the release of pathogens from containment after screening; and
- g) Packaging and transshipment of pathogens in such a manner as to prevent their escape during transport.

Ultimate responsibility for the release of pathogens from the containment facility rests with the Research Leader of the facility, who in certain cases may himself be designated Containment Officer.

Other personnel assigned to the containment program will be limited in number, and thoroughly instructed in the operational procedures. A list of personnel authorized access to the containment area will be prepared and prominently posted. All other personnel will be denied access to these areas unless accompanied by the Containment Officer or his designated representative.

2. Operational Procedures.

Each ARS Containment Facility will prepare specialized operational procedures, which may differ depending on the location, primary mission, physical construction, and staffing of the facility. These operational procedures will be approved by appropriate ARS line and staff officials, and by APHIS and State regulatory officials prior to issuance of an importation permit and certificate authorizing operation of the facility as a Containment Facility for receipt of foreign microbial biological control agents for arthropod plant pests and/or medical and veterinary pests, whichever may be the case. The approved Operational Procedures will be posted near the entrance of the containment area of the facility. APHIS officials will conduct periodic unannounced inspections of the facility to ascertain that these procedures are being followed, and State regulatory officials may also conduct such inspections.

Operational procedures must include:

- a) Permit and approval procedures for importations (see Section III.A), including provision for handling unsolicited shipments arriving without proper permits or approvals, and for following other specific procedures as may be stipulated in the importation permit.
- b) Provisions for assuring maintenance of containment conditions, including limited access to containment areas, and requirements for protective clothing, etc.
- c) Provision for opening of incoming shipments in special containment areas within the main containment area or in a Class 2, Type A biological containment cabinet.
- d) Description of means of destruction or sterilization of shipping containers and packing material within containment.
- e) Means for screening in containment of imported material and for elimination of inadvertently, inappropriately, or necessarily included organisms such as plant material, arthropod hosts, or contaminants. In all cases, only healthy domestic host material will be used if required to maintain cultures of pathogens, under special containment conditions.

f) Means for obtaining rapid authoritative identification of pathogen species received in containment, to the extent as may be required. Cultures or specimens should be submitted for identification with the most complete possible information about the pathogen, original (and any subsequent) hosts, location at which the material was collected, and any pertinent identification numbers given by its collector or submitter; much of this information will be provided in properly completed AD-944 forms. Identifications will be done to the greatest possible extent by staff of the receiving containment facility, but may be submitted to other specific specialists as appropriate for confirmation or for a definitive identification. See Weiser and Briggs (1971) for general techniques for specimen preparation and for procedures for submitting specimens for identification; further more specialized information about preparing and submitting fungal specimens is found in Hawksworth (1974) and Stevens (1974).

g) Detailed protocol to be followed prior to release of organisms from maximum containment area for further testing as required, or prior to the decision to release organisms from containment for further shipment or field release. This protocol should include consideration of the known or tested host range and relationships of the species or of the taxonomic group to which it belongs, its potential effect on other beneficial organisms, adequacy of safeguards for elimination of contaminants, adequacy of taxonomic identifications, and other safety considerations listed in Section II.B of these Guidelines. See also Section V of these Guidelines.

h) Means for storage in containment of the imported pathogens.

i) Shipping procedures, including proper packaging, and documentation procedures (see Section V.C of these Guidelines).

j) Documentation procedures (see Sections III.C, IV.C, and V.E of these Guidelines).

k) Voucher procedures (see Section V.F of these Guidelines).

l) Provisions for monitoring of the Operational Procedures by the Research Leader or Laboratory Chief of the Containment Facility.

C. Documentation of Receipt of Imported Material.

The Containment Officer of each approved ARS pathogen receiving facility is responsible for completion of Section II of **proposed** AD Form 944 (Attachment 5), which is to accompany each shipment of foreign material received (see Section III.C of these Guidelines), and for filing and distribution of the copies of this form according to instructions on the form. The Containment Officer is also responsible for assuring that these forms are included in all incoming shipments, or for their preparation if not so included.

A record of all shipments and species received in the receiving facility will be periodically provided to BCDC, PPQ (and VS if appropriate), and the pertinent State regulatory agency, as may be stipulated in the importation permit. (See also Section V.E for additional records to be provided by the receiving facility).

The Containment Officer should retain properly preserved specimens of incoming material, and of original host material, if available, to serve as vouchers representing material received in quarantine. See Section V.F for additional information concerning voucher specimens.

V. Consignment from Containment, Interstate Shipment, and Field Release of Foreign Microbial Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests.

The ultimate responsibility for the release of an organism from containment rests with the Research Leader or Laboratory Chief of the ARS receiving facility, although authority for making this decision may be delegated to a designated Containment Officer under certain circumstances. Procedures and considerations required prior to release from containment are included in the Operational Procedures approved by APHIS (see Sections IV.B.2.g and V.A-F of these Guidelines). The Containment Officer is responsible for: 1) Assurance that safety considerations (see Section II.B) are made prior to release of the organism from containment conditions, or that proper arrangements are made for any additional testing deemed to be required; 2) Documentation procedures involved following release from containment; 3) Preparation of voucher specimens as appropriate; and 4) Assurance that any necessary authorizations for interstate shipment and/or field release of the organism are obtained (see Sections V.B-C below).

A. Safety Considerations and Testing, and Clearance for Removal from Containment.

Included in the Operational Procedures, which are approved by APHIS and the pertinent State regulatory agency, are detailed protocols to be followed prior to release of organisms from containment (see Section IV.B.2.g). These protocols include review, clearance, and testing procedures required prior to release of foreign pathogens from containment.

1. Review and Clearance Procedures.

The first step in containment clearance procedures must be to obtain an authoritative morphological and/or biological identification of the organism, at least to the lowest appropriate taxonomic level possible (see Section IV.B.2.f); the level to which identifications of microbes should be made prior to release from containment will vary according to the particular class to which the organism belongs and to the considered judgement of the individual bearing ultimate responsibility for authorizing the organism's release from containment. No live material with insufficiently known host relationships will be permitted to leave containment. The Containment Officer, with the pertinent researcher involved with the organism, will determine clearance for release of an organism from quarantine by means of a critical review of available ecological and biological information based on the taxonomic identification of the organism and discussions with relevant knowledgeable experts, including microbiologists and biological control research workers. During this review, special attention will be paid to the two main areas of safety considerations listed in Section II.B.2 of these Guidelines. Based on this review of information and discussions, conclusions are reached by the Containment Officer by which the identified pathogen is assigned to one of three containment clearance categories:

Class A: The pathogen is considered dangerous or otherwise unsuited for continued experimentation. All material placed in this category must be destroyed in containment.

Class C: The pathogen is considered a promising biological control agent, but specific additional studies are deemed necessary before field release can be permitted. Material placed in this category may be given clearance for consignment to other researchers within the receiving facility or for interstate or other shipment to appropriate researchers at other facilities of such design as to prevent escape during conduct of the needed studies. See Section V.B for further procedures.

Class D: The pathogen is considered safe for field release in the U.S., based on previous release clearance. Pathogens placed in this category may be consigned to non-containment personnel of the receiving facility for field release or shipped interstate following procedures stipulated under Sections V.B-C.

2. Testing under Containment.

Included in the two areas of safety considerations listed in Section II.B, is the need for information that may require testing of the organism under containment conditions. This includes the following considerations:

- a. Tests to assure that all contaminants have been removed from the material to be consigned from containment.
- b. Mycoplasmas must be retained in containment (Class III Biological Containment Cabinets) until their spectrum of activity on both plants and animals is thoroughly understood.
- c. If rickettsia are found in dead arthropods received in containment, all material received should be destroyed in containment (see Section II.B).
- d. Any pathogens of biting insects, ticks, or other vectors of vertebrate disease should be authoritatively identified and submitted to animal testing before release from containment. See FIFRA Guidelines.
- e. Certain protozoa (e.g., *Coccidia*) and viruses (e.g., entomopox viruses) require animal testing before removal from containment (see Section II.B above and FIFRA Guidelines).
- f. Fungal pathogens require cultivation in containment until identified as non-vertebrate pathogens.
- g. Bacteria and other pathogens requiring propagation in susceptible arthropods must be so propagated under containment conditions. Arthropods must be of domestic origin, unless special APHIS permits have been received, and must be securely caged in containment.
- h. Most foreign pathogens need testing on confined honey bees and other selected beneficial arthropods, with particular consideration for any possible harmful effects against endangered or threatened species (which may not be directly tested for susceptibility to the foreign pathogen), prior to field release in the United States (see Sections II.B. and IV.B.2.g). Such tests may or may not need to be conducted in containment, at the discretion of the Containment Officer.

Some of the information needed for eventual field release of pathogens placed in Class C (see Section V.A.1) may include data that must be accumulated by the tests indicated above. Emphasis should also be placed on obtaining such information from field studies in the country of origin if possible, rather than relying solely on results of laboratory tests.

If, following containment testing of the organism, any doubt remains concerning the propriety of release of the organism from containment, the matter may be placed before a panel of appropriate scientists [PHRASE RETAINED PENDING ARS AND APHIS DECISIONS.] and/or the BCAC for arbitration (see Section V.D). It is important that any potential harmful effects of a pathogen of arthropod plant or animal pests indicated by such laboratory tests be critically weighed against the potential beneficial effects of the pathogen and the evidence obtained from field studies and published information concerning the pathogen where it occurs in nature.

B. Interstate Shipment from Facilities Engaged in Receipt, Propagation, or Storage of Introduced Microbial Biological Control Agents for Arthropod Pests.

The intended recipient of foreign microbial biological control agents for arthropod pests to be shipped through or otherwise received from ARS containment facilities, or from non-containment facilities, shall be responsible for ascertaining whether any State approvals for such shipments exist in the State in which the pathogen is to be received, and for obtaining those permits as required. In general, there is no requirement for APHIS permits for interstate movement of foreign pathogens assigned to Classes C and D (see Section V.A.1 above). However, if the material is to be released in the field by the recipient, this intent must be clearly indicated, in which case the Containment Officer, or other responsible official, of the ARS shipping/receiving facility must ascertain whether the necessary approvals for such release, as noted in Section V.C below, have been obtained before shipment of the pathogens can be made.

If State approval for the shipment is required, the PPQ Form 526 or PPQ/ARS Form __ can be used to obtain the approval, and a copy of the completed form will be forwarded by the proposed shipment recipient to the ARS containment or non-containment facility making the shipment, after which the shipment(s) may be made. The Containment Officer or pertinent non-containment personnel will maintain a file of such State approvals, and will provide copies to APHIS and BCDC upon request.

Arrangements for State approvals and/or APHIS permits for field releases must be made well in advance of intended shipments, to prevent the loss of valuable live materials while awaiting approval procedures.

All foreign arthropod biological control agents shipped from ARS facilities will: 1) be packaged in containers designed to prevent breakage or escape of the pathogens during transport (see Section III.B); 2) a PPQ "courtesy" shipping label authorizing interstate shipment affixed to the outside of the package, and 3) be accompanied by shipping record forms (see Section V.E).

APHIS-approved ARS containment receiving facilities may obtain a supply of APHIS courtesy shipping labels from APHIS or BCDC for use for shipments of pure cultures of microbial biological control agents under the permit issued for operation as a primary receiving facility (see Section IV), for shipment to States not requiring a permit. These courtesy shipping labels will not be used for the rare cases in which live host materials (arthropod pests) or plant material are to be included in the shipments; in these cases, specific APHIS-issued permits and permit labels are required. No interstate shipments will be made by ARS facilities except under the conditions stipulated in the facilities' importation permit received from APHIS for its operation.

ARS facilities involved in interstate shipment of foreign organisms will maintain a record of such shipments and will provide, upon request, such records to appropriate regulatory agencies in the State in which the facility is located and to regulatory agencies of the States to which shipments have been made. APHIS and BCDC shall be similarly informed, upon request. The Containment Officer(s) shall be responsible for such notification for ARS containment facilities. The preparation of annual shipment reports is highly recommended. See also Section V.E below for **proposed** use of the AD Form 944 in connection with interstate shipments of foreign material.

C. Field Release of Foreign Microbial Biological Control Agents for Arthropod Plant and Medical and Veterinary Pests.

1. General Approval and Permit Requirements.

Specific approval procedures for field release of foreign microbial biological control agents for arthropod pests cleared for release from containment under procedures indicated in Section V.A above, will include: a) A requirement for State approval and an APHIS permit for the initial field release of an exotic species in the United States, which may require submission of an Environmental Assessment (EA); b) A requirement for an Experimental Use Permit (EUP) from the Environmental Protection Agency for field testing involving 10 acres or more of any microbial pathogen, foreign or domestic, during development of a microbial pesticide; c) A requirement for an APHIS permit and State approval for all subsequent field releases of the approved foreign pathogen in other States; and d) Proper documentation of all initial and subsequent field releases of foreign pathogens, including periodic notification of APHIS, BCDC, and pertinent State agencies. The Research Leader and other involved ARS personnel at ARS facilities proposing to release foreign arthropod pathogens for field testing or establishment are responsible for adherence to these procedures.

All applications for State approvals and APHIS permits for field release of foreign pathogens of arthropods for field testing or establishment shall be initiated by use of PPQ Form 526 (Attachment 1).

2. Federal and State Regulations.

Provisions must be made to meet the requirements of certain Federal and State regulations impacting the introduction of exotic organisms for biological control of pests. The Federal regulations involved, in addition to the Plant Quarantine Act (PQA) and Federal Plant Pest Act (FPPA) already mentioned in these Guidelines as regulating the importation and movement of live organisms, include the following: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the National Environmental Policy Act (NEPA); the Endangered Species Act (ESA); and the Federal Food, Drug, and Cosmetic Act (FFDCA). The ARS Research Leader, Containment Officer, and involved researchers, are responsible for adherence to the requirements of regulations under these Acts as noted below.

FIFRA: Under this Act, which is administered by the Environmental Protection Agency (EPA), all biological agents used for control of pests are classified as pesticides, and thus their movement and use is regulated by EPA. EPA has exempted from regulation under FIFRA invertebrate biological

control organisms on the grounds that they are adequately regulated by the USDA, primarily by APHIS under the PQA and FPPA and associated regulations. However, EPA regulations under FIFRA must be followed in the development of microbial pesticide products. EPA guidelines for microbial pesticides appear in 40 CFR Part 158 Subpart M, Part A "Microbial Pest Control Agents." Note: Those guidelines do not cover importation or other movement of such agents.

NEPA: Under this Act, all Federal or Federally-supported agencies must consider the environmental impact of major actions that may significantly affect the quality of the human environment in the U.S. USDA agencies interpret this to mean that, with certain exceptions, a formal Environmental Assessment (EA) is required for the initial field release of exotic biological control agents in the U.S. That is, an environmental risk analysis must be applied in such actions by ARS (ARS, 1986), and for the issuance of Federal permits by APHIS for the initial field release of introduced plant pests or potential plant pests. [THE FOLLOWING SECTIONS ARE RETAINED PENDING DECISIONS AND ACTIONS BY ARS AND APHIS.] A proposed list has been prepared by ARS and other scientists of beneficial microbial organisms that offer little or no risk of having significant adverse effects on the quality of the environment, and thus are exempt from this requirement (see Attachment 7). The proposed criteria for excluding these organisms from the EA requirement prior to issuance of an APHIS permit are listed on Attachment 8 [NOTE: THESE CRITERIA NEED TO BE REFINED BY A SCIENTIFIC PANEL]. The list of exempted organisms may be amended by application to the ARS and/or APHIS Administrators. APHIS may issue permits for the initial release of the types of organisms represented on the list without preparation of a formal EA, but may require applicants to submit additional information in lieu of an EA to resolve questions about the proposed release of a biological control agent.

For initial release of organisms *not* exempted from a formal EA requirement, environmental assessment protocols have been prepared, the complexity of which vary with the level of risk involved. Attachments 9 and 10 present formats for providing APHIS with information required for their preparation of an EA prior to issuance of a permit for initial release of non-exempted organisms. Attachment 11 provides the criteria used to derive these protocols. [NOTE: ATTACHMENT 11 NEEDS TO BE PREPARED BY A SCIENTIFIC PANEL] In cases where the level of risk is high, an Environmental Impact Statement (EIS) would be required. For non-exempted microbial biological control agents for arthropod pests, the "short" format (Attachment 8) may generally be used, together with PPQ form 526, for requesting APHIS permits for initial release. See Section V.D for the role of the BCAC in these procedures. [END OF RETAINED SECTIONS]

ESA: This Act, administered by the Fish and Wildlife Service (FWS) of the USDI, concerns the impact of Federal actions on native endangered and threatened animals (including arthropods) and plants in the U.S. The safety evaluations noted in Sections II.B.2.b and V.A.2.h are designed to meet these concerns. Comments on these concerns and results of any test results related to them should be noted on the permit application or EA protocol document.

FFDCA: This Act, administered by the Food and Drug Administration (FDA), impacts on the use of arthropod pathogens to control pests in stored food products; these are considered pesticides and are subject to the requirements for tolerances under FFDCA. When applying for a permit for the initial release of any microbial natural enemy for use in stored products not exempted from requirement of a tolerance, an evaluation of its potential as an adulterant of foodstuffs must be made, and comments on this evaluation should be made on the permit application or EA protocol document.

Several States have laws and regulations regarding environmental policy and/or endangered species within their boundaries, similar to NEPA and ESA. In addition, certain States have regulations requiring permits or approval prior to shipment or release of organisms within their borders, or have otherwise formally requested notification prior to such importations or releases (see Attachment 12). Knowledge of and adherence to pertinent State regulations are responsibilities of the involved ARS Research Leader, Containment Officer, and other involved researchers prior to the initial and subsequent releases of microbial and other biological control organisms in the United States.

3. Initial Releases of Microbial Biological Control Agents of Arthropod Pests in the United States.

Prior to initial field releases of new microbial biological control agents for arthropod pests in the United States, appropriate State approval(s) and an APHIS permit must be obtained on PPQ form 526 (Attachment 1) by the ARS containment facility or other facility proposing to make the initial release. Section A of form will be completed by the facility indicating the intent to field release the biological control agent in the State, and the form will be sent to the pertinent State regulatory agency (see Attachment 3), along with an Environmental Assessment protocol document if required (see NEPA requirements above). If an EA is deemed not to be required, it must be documented on the permit application that criteria for exclusion of the organism from the EA requirement have been met. State approval will be indicated in Section B of the form, and the form will be forwarded by the State official to APHIS for completion of Section C indicating approval or disapproval of the release.

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY EITHER ARS OR APHIS OR BOTH.]

If an EA is required, there are then two possible scenarios:

(1) An appropriate EA protocol document (see NEPA requirements above and Attachments 9-11) will be prepared by the permit applicant and included with the appropriate permit application form (PPQ form 526) when submitted to the State regulatory official in which the initial field release is intended. State approval will be indicated in Section B of the form, and the form will be forwarded by the State official to APHIS, where the document will receive an in-house review in APHIS, and/or by BCAC as may be requested. After a favorable review, APHIS will prepare an EA and, if this results in a Finding of No Significant Impact (FONSI), APHIS-PPQ will complete Section C of the permit application form. PPQ will return the completed form (which constitutes the permit) to the applicant, with copies to the involved containment facility (if this differs from that of the applicant), and to the BCDC and the pertinent State regulatory agency. The permits, valid for 5 years, may be renewed for another 5-year period, after which no further permits for release of the permitted organism in that State shall be required. The Quarantine Officer shall be responsible for permit renewals.

(2) For the second option, the ARS researcher proposing the initial U.S. field release of an introduced biological control agent will submit the appropriate EA protocol documents (see Attachments 9-11) to the pertinent ARS office for review. If judged to be appropriate, a FONSI will subsequently be prepared by ARS which will then be included with the permit application form when sent to APHIS via the appropriate State regulatory agency. APHIS-PPQ may then issue the permit and send copies as in Option 1. ARS will also notify EPA of the intended release with copies of all appropriate

environmental documents, in order to comply with the current requirement of EPA notification of field studies of microbial organisms. [END OF RETAINED SECTIONS]

These procedures currently pertain only to experimental field releases in test plots of less than 10 acres (or less than one acre for applications to be made to bodies of water). If field tests are required in larger areas, an EUP must be obtained from the EPA.

Though not required, it is highly recommended that studies of the "native" pathogens infecting the target arthropod and its close relatives in the initial and subsequent release areas be conducted prior to release of the foreign pathogen, in order that its establishment and spread may be better documented.

4. Subsequent Releases of Microbial Biological Control Agents for Arthropod Pests.

Completion by the Containment Facility or other shipping/releasing facilities of Section A of the PPQ Form 526 for State regulatory agencies is also required for subsequent releases of the same organism in additional States. As for initial release, the PPQ Form 526 will be forwarded, if release is approved, by the State official to APHIS-PPQ. Based upon prior release approval and State recommendation, PPQ will complete Section C and distribute copies of the completed form (the permit) as above.

[THE FOLLOWING SECTIONS CONTAIN PROPOSALS AND ARE RETAINED PENDING DECISIONS AND ACTIONS BY ARS, APHIS, OR OTHER AGENCIES.]

For certain initial releases in the State in which the Containment Facility is located of organisms exempted from the requirement of an environmental assessment, PPQ and/or State approval *may* be obtained on the same PPQ Form 526 used for requesting importation permits (see Section III.A), by indicating the intent to release on the form when first submitted. In certain cases, State regulatory officials may elect to issue "blanket authorizations" for releases of specified imported microbial biological control agents, in consultation with the Containment Facility and APHIS. In other cases, telephone approvals may be obtained as required in emergency situations; these should be documented in writing as soon as possible. In other cases, State or APHIS officials may elect to request an opinion on proposed releases from BCAC (see Section V.D).

After permits are obtained for their initial releases, no other prior action, except permit renewal as noted above, is required for subsequent field release of imported microbial biological control agents in States for which permits have been received. However, appropriate regulatory agencies in all States in which field releases are made shall routinely be informed periodically in writing of all releases made within their boundaries by ARS personnel. APHIS and BCDC shall also be similarly informed.

D. Interagency Biological Control Advisory Committee (BCAC).

The BCAC is an interagency advisory group [proposed to be] established to provide technical support and advice to ARS and/or APHIS, upon request: (1) in evaluating risks with specific requests for permits to import or release exotic biological control agents; and (2) in establishing criteria for appropriate evaluation of requests for permits involving biological control organisms. The BCAC will not

be involved in making regulatory decisions; it will be consulted regarding proposed importations and releases, primarily in regard to environmental safety factors, in cases in which Federal or State regulatory agencies seek further scientific input to make a regulatory decision, and can serve to resolve any substantive disagreements between APHIS and applicants, or upon specific appeal by biological control research workers, etc. See Attachment 13 for an outline of procedures involving BCAC for providing APHIS and/or ARS with such technical support, and Section V.B above for specific information in regard to its involvement in field releases of introduced biological control agents. All communications with BCAC should be addressed to its Executive Secretary.

After final review of information concerning microbial biological control agents assigned to Class C (see Section V.A.1), including information resulting from tests conducted in containment and other facilities, if any doubt remains as to the propriety of release of the pathogen from containment status, the question may be placed before BCAC for an informal review. This may be done by the Containment Officer of the facility in which the tests were conducted, or by research workers at that or other facilities who are interested in obtaining clearance for such release. Documentary evidence pro and con will be accumulated for presentation to BCAC, together with an explanatory memo stating the position of the involved Containment Facility, and supportive or contradictory memoranda from interested research and regulatory officials. BCAC will respond with a consensus opinion indicating support or lack of support for the proposed action. If the consensus opinion is favorable, the Containment Facility can proceed with field release or interstate procedures, in which the BCAC may be more formally involved (see Sections V.B-C).

[END OF RETAINED SECTIONS]

E. Documentation of Shipments and Field Releases of Introduced Microbial Biological Control Agents for Arthropod Pests.

A photocopy of the original proposed AD Form 944 documenting initial importation of the foreign material should be included with all consignments and shipments of foreign pathogens made by ARS containment receiving facilities, with notes on any passages in hosts other than the original host. It is highly recommended that all other ARS researchers provide copies of the original AD Form 944 and similar notes for all subsequent shipments of the foreign pathogen material.

As noted in Section V.B above, ARS containment facilities approved for initial receipt of foreign pathogens will maintain a record of all shipments of these pathogens and provide a written record, upon request, to appropriate regulatory agencies in the State in which the containment facility is located, to such agencies of other States to which shipments have been made, and to APHIS and BCDC. The Containment Officer(s) shall be responsible for such notification.

The field release of pathogens cleared for field release in accordance with procedures outlined in Section V.A-C should be documented by use of the proposed AD Form 944A (Attachment 14), following instructions on the form. A single AD Form 944A may be used to record multiple releases, noting a range of release dates in Section II of the form. This form provides source, culture, and other information to document the field release. Copies of the completed form should be sent to the pertinent ARS receiving facility, to BCDC, and APHIS-PPQ.

All ARS containment facilities and BCDC will be provided with supplies of AD Form 944A and will provide, upon request, supplies of these forms to persons and facilities engaged in culture, shipment, and release activities.

The Containment Officer of each ARS pathogen containment receiving facility shall be responsible for assuring proper documentation of consignments, shipments, and/or releases of foreign microbial biological control agents, using AD Forms 944 and 944A, and for distribution of the copies of the forms.

F. Voucher Specimens.

Retention of specimens representing imported and released material is required in some cases, and is highly recommended in all cases, in order that vouchers relating to the importation and release of exotic organisms in the United States will be available for immediate or future study by taxonomists and biological control researchers.

Of particular importance are voucher specimens to document:

- 1) The first field release in the United States of a foreign microbial biological control agent by containment or other facilities; these voucher specimens should include specimens from each major geographical area (at least from each country) of origin of the released material;
- 2) Subsequent field releases of the same species from new major geographical areas;
- 3) Field releases from long-established laboratory or storage cultures; and
- 4) The first additional field release of a newly imported foreign species if such releases are resumed after a period of three or more years after initial field release.

5) Retention of voucher specimens of the original and laboratory arthropod hosts, and target hosts, is also highly recommended. See Steyskal et al. (1986) for information on the preparation of arthropod specimens. Voucher specimens and, wherever possible, cultures should be prepared of microbial pathogens being released as well as of infected target hosts regarded as being infected by the released pathogen. Voucher materials should be deposited with the appropriate ARS containment facility handling the particular pathogen; additional depositions of voucher specimens and/or cultures in other suitable repositories is encouraged [ATTACHMENT RETAINED PENDING DECISIONS BY ARS] (see Attachment 15).

See Weiser and Briggs (1971), Hawksworth (1974), Stevens (1974), Alexander and Branden (1986) for information on the preparation and shipment of reference specimens and cultures.

VI. Export of Microbial Biological Control Agents for Arthropod Pests to Other Countries.

All ARS domestic and overseas facilities and personnel making shipments of microbial biological control agents to foreign countries for research purposes will determine whether or not quarantine regulations exist in the country to which the shipment are to be made, including any requirement for quarantine entry permits, and are responsible for adherence to those regulations, if any.

All shipments to foreign countries shall be shipped in containers designed to prevent escape of organisms. Host materials (arthropod or plant) will not be included in the shipments unless absolutely

required, and unless specific approval for such inclusion is obtained from the foreign government.

[PARAGRAPH RETAINED PENDING DECISIONS BY ARS AND APHIS.] Although not legally required, it is highly recommended that an APHIS-PPQ shipping permit label (or equivalent ARS form to be developed) be affixed to the outside of the package near the address labels, together with the foreign permit label, if applicable. These shipping permit labels may be obtained from ARS-BCDC, who will issue the labels only after receipt of documentary evidence that all foreign quarantine regulations have been met or that there are no quarantine regulations (e.g., photocopies of permits or relevant correspondence). [END OF RETAINED PARAGRAPH]

As a courtesy and for the information of the foreign recipient, an AD Form 944 shipment record form (Attachment 5), with Section I completed, should accompany each shipment, with a request that Section II of the form be completed, and the form returned to the sender. The sender is responsible for distribution of copies of the **proposed** form in accordance with instructions on the form.

Although no voucher specimens are required, it is highly recommended that the sender of shipments to foreign countries retain such specimens to document the contents of the shipments for possible future reference.

VII. Recommended References.

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Steyskal, G. C., W. L. Murphy, and E. M. Hoover. 1986. Insects and Mites: Techniques for Collection and Preservation. U.S. Dept. Agr., Misc. Publ. 1443, 103 p.

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PPQ Form 526: Application and Permit to Move Live Plant Pests or Noxious Weeds

SEE NO. 1 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed PPQ/ARS Form __: Application and Permit to Move Living Beneficial Organisms

SEE NO. 2 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

List of Plant Regulatory Officials of U.S. States and Territories, Canada, and Mexico

SEE NO. 3 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

VS Form 16-3: Application for Permit to Import or Transport Organisms or Vectors

SEE NO. 4 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Draft AD Form 944: Record of Shipment of Exotic Microorganisms for Biological Control

SEE NO. 19 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

List of ARS Biological Control Containment Facilities **Proposed to be** Approved for Initial Receipt of Foreign Microbial Biological Control Agents for Arthropod Pests

TO BE PREPARED

Draft Guidelines (D, page 29)

**Proposed List of Microbial Biological Control Agents
for Arthropod Pests Exempted from the Requirement
of a Formal Environmental Assessment**

VIRUSES:

Baculoviruses

BACTERIA:

. *Bacillus thuringiensis* var. *israelensis*

MICROSPORIDIA:

All species of the genera *Amblyospora* and *Vairomorpha*

FUNGI:

Oomycetes: Lagenidiales

Lagenidium giganteum

Zygomycetes: Entomophthorales

Family Entomophthoraceae

Batkoa: all species

Entomophaga: all species

Entomophthora: all species

Erynia: all species

Furia: all species

Pandora: all species

Zoophthora: all species

Family: Ancylistaceae

Conidiobolus obscurus, *thromboides*

Family: Neozygitaceae

Neozygites: all species

Deuteromycotina:

NOTE: All deuteromycetes proposed hereunder for exemption include ALL alternative conidial (synanamorphic) and/or sexual (teleomorphic) states.

Hyphomycetes:

Beauveria bassiana, *brongniartii*

Hirsutella: all species

Metarhizium: all species

Nomuraea rileyi

Verticillium lecanii

Coelomycetes:

Aschersonia: all species

[THIS LIST AND THE CRITERIA FOR EXEMPTION (ATTACHMENT 8) NEEDS FURTHER REVIEW BY SCIENTIFIC PANEL]

Draft Guidelines (D, page 30)

**Proposed Criteria for Exemption
of Microbial Biological Control Agents for Arthropod Pests
from the Requirement of a Formal Environmental Assessment for Field Release**

[NOTE: The following criteria for exemption of microorganisms in general were developed at an EA Protocol Workshop at Beltsville, MD, in May 1989.

"All non-pathogens -- plant, insect, animal, human

If pathogenic, then consider:

- a. Ubiquity (not known to have hypervirulent strains)
- b. Host specificity
- c. Occurrence of non-target effects
- d. Genetic stability and gene immobility
- e. Environmental persistence and reproductive potential
- f. Dispersion capability"

Using these general factors, a more specific criteria is required for listing specific groups of or individual arthropod pathogens as exempted from an EA requirement. SUCH CRITERIA NEED PREPARATION BY A SCIENTIFIC PANEL.]

**Proposed Abbreviated Protocol Document for Providing Data for
Preparation of Environmental Assessments (EA)
upon which Decisions will be Based for Issuance of Permits
for Initial Field Release in the United States
of Exotic Microbial Biological Control Agents of Arthropods
(Short Format)
Request for Environmental Evaluation
for Release of Potential Plant Pests**

Please provide information that addresses the subjects listed below. This information is needed to determine plant pest risk and impact on the environment for any request to release non-exempted microbial pathogens into the environment from PPQ-approved quarantine or other containment facilities for the purpose of biological control of invertebrate pests, especially insects or mites.

1. Purpose and need for release.
2. Alternatives (i.e., pesticides; no action) to the release.
3. Test organism.
 - a. Identification and taxonomy of organism to be released. Name(s) and affiliation(s) of identifiers.
 - b. Geographic distribution and ecological profile of organism where it was originally collected or isolated.
 - c. Host specificity of organism to be released, including effects to non-target organisms, especially those considered beneficial or endangered.
 - d. Provision for exclusion of contaminants, hyperparasites, and other organisms from release material.
4. Target host or prey.
 - a. Distribution and economic impact, detrimental and beneficial. Are there conflicts of interest?
 - b. Brief statement of life history and ecology, including environmental profile.

5. Description of field experiment.
 - a. Number and whereabouts of release sites.
 - b. Quantity and form of microbe to be released.
 - c. Time and season of release(s).
 - d. Provisions for monitoring of release(s), including containment or removal provisions if problems arise.
6. General statement of environmental effects of release(s).
 - a. Affected environment -- specific elements should include (but are not limited to) plants, soil, water, air, wildlife, threatened and endangered species, livestock, and human populations.
 - b. Non-target effects: Does the pathogen to be released attack an economic crop, humans or animals, beneficial arthropod species, or endangered species? Is it a potential nuisance to humans or domestic animals?
 - c. Any unavoidable adverse effects of release?
 - d. Potential for dispersal of the released organism? Can it be contained in the field?
 - e. Mitigating circumstances.
 - f. Researcher's recommendation.
7. List any known prior USDA permits for this and similar organisms.
8. Pertinent references.

[THIS PROTOCOL DOCUMENT NEEDS FURTHER REVIEW BY SCIENTIFIC PANEL, TO INCLUDE REGULATORY OFFICIALS.]

Proposed Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Biological Control Agents: Long Format

SEE NO. 11 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Attachment 11

Proposed Criteria for Microbial Biological Control Agents Requiring Only an Abbreviated Protocol Document for Providing Environmental Assessment Information

NO. 12 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES PROVIDES SUCH CRITERIA FOR INVERTEBRATE ORGANISMS; SUCH CRITERIA FOR ARTHROPOD PATHOGENS NEED TO BE DEVELOPED BY A SCIENTIFIC PANEL OF ENTOMOPATHOLOGISTS

Attachment 12

List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries

SEE NO. 13 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES
TO BE PREPARED

Attachment 13

Proposed Structure and Procedures of the Proposed Biological Control Advisory Committee (BCAC)

SEE NO. 7 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Attachment 14

Draft AD Form 944A: Documentation of Release of Exotic Microorganisms for Biological Control

SEE NO. 20 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Draft Guidelines (D, page 34)

Proposed ARS Repositories for Cultures of Microbial Biological Control Agents for Arthropods

**THIS ATTACHMENT NEEDS COMPLETION AFTER CONSIDERATION BY ARS
ADMINISTRATORS AND SCIENTISTS**

Draft Guidelines (D, page 35)

**Proposed ARS Guidelines for
the Importation, Interstate Movement, and Field Release in the United States
of Foreign Pathogens for Biological Control of Weeds, and for the
Interstate Movement and Export of Foreign and Native Pathogens of Weeds ¹**

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Attachments

1. Charter of the Technical Advisory Group on Introduction of Biological Control Agents of Weeds, and List of its Organizational Members
2. PPQ Form 526: Application and Permit to Move Live Plant Pests and Noxious Weeds
3. List of Biological Control Quarantine/Containment Facilities **Proposed to be** Approved for Initial Receipt of Foreign Pathogens for Biological Control of Weeds
4. List of Plant Regulatory Officials of U.S. States and Territories
5. **Proposed** Guidelines for U.S. Importation of Exotic Natural Enemies of Weeds from Canada
6. **Proposed** AD Form 944: Record of Shipment of Exotic Microorganisms for Biological Control
7. **Proposed** Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Release of Biological Control Agents of Weeds: Long Format
8. List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries
9. Structure and Procedures of the **Proposed** Biological Control Advisory Committee (BCAC)
10. **Proposed** AD Form 944A: Documentation of Release of Exotic Microorganisms for Biological Control

¹ Original draft prepared by J. R. Coulson from 1978 draft material by H. L. Walker, R. J. Smith, and C. H. Kingsolver (ARS); revisions by W. L. Bruckart and J. R. Coulson, with comments provided R. Charudattan (University of Florida), and following review by Working Session participants (see Appendix 1) in January, 1991.

I. Intent and Scope of these Guidelines.

Importations of invertebrate natural enemies from other countries for biological control of weeds in the continental U.S. began in the 1940s; such introductions of exotic weed pathogens did not begin until 1978. Over the years, procedures were developed by U.S. researchers to assure that such importations were conducted with the maximum possible safety to U.S. agriculture and environment. In the 1970's, the USDA Agricultural Research Service (ARS) Working Group on Natural Enemies of Insects, Weeds, and other Pests was formed, which began the process of codifying these guidelines for ARS scientists. These current Guidelines, which are the result of input from many ARS and other scientists, are intended to provide detailed procedures required for the importation, interstate shipment, and field release of foreign pathogens of weeds for biological control research and development programs in the United States. These procedures are designed to insure that every reasonable precaution will be taken to contain and prevent the escape or release of organisms that are injurious to agricultural, horticultural, or forestry commodities, humans and domestic animals, or other beneficial organisms, or that are otherwise detrimental to the environment.

Organisms for which these Guidelines are intended include both exotic (foreign) plant pathogens intended for biological control of weedy plants and any associated host plant material. The pathogens include species, strains, or pathotypes of phytopathogenic fungi, bacteria, viruses, mycoplasmas, and other microbial organisms. Guidelines for the containment of these organisms are necessary to insure the safe shipment and study of potentially beneficial microbials until adequate knowledge is developed regarding their safety. If data from containment research indicate an organism may threaten North American plant species of economic or ecologic importance, a decision can be made to destroy the organism while it remains under control in containment. If data from containment research indicate an organism does not present a hazard to the U.S. environment, further guidelines are needed to provide for its safe release from containment or its field release for biological control purposes.

These Guidelines also include procedures for the interstate movement and export of foreign or domestic microbial pathogens of weeds to other countries for research purposes.

Separate Guidelines exist for importing and releasing foreign arthropods and nematodes for control of weeds, various other foreign invertebrate and microbial organisms for control of invertebrate pests and plant pathogens, and pollinating invertebrates. Field testing, development, and utilization of microbial pathogens of domestic origin in the United States will be guided by separate authority and guidelines.

Some organizational abbreviations used in these Guidelines are:

APHIS - Animal and Plant Health Inspection Service, USDA

ARS - Agricultural Research Service, USDA

BCAC - Interagency Biological Control Advisory Committee Proposed

BCDC - Biological Control Documentation Center, ARS

EPA - Environmental Protection Agency

FDWSRU - Foreign Disease-Weed Science Research Unit, ARS

FWS - Fish and Wildlife Service, USDI

NPS - National Program Staff, ARS

PPQ - Plant Protection and Quarantine, APHIS

SBML - Systematic Botany and Mycology Laboratory, ARS

SWSL - Southern Weed Science Laboratory, ARS
TAGIBCAW - Technical Advisory Group on the Introduction of Biological
Control Agents of Weeds
USDA - United States Department of Agriculture
USDI - United States Department of Interior

II. Summary of Procedural Policies and General Safety Considerations.

A. Summary of Procedures for Importation, Interstate Shipment, Field Release, and Export of Microbial Biological Control Agents for Weeds.

The Plant Quarantine Act of 1912 and the Federal Plant Pest Act of 1957 prohibit the importation and movement of plant and animal pests, pathogens, vectors, and articles that might harbor these organisms, unless authorized by the U.S. Department of Agriculture (USDA). The National Environmental Policy Act of 1969 (NEPA) contains provisions that impact upon the release of exotic organisms into the environment. Regulations under these Acts are enforced by the Plant Protection and Quarantine Programs (PPQ) and Veterinary Services (VS) of the Animal and Plant Health Inspection Service (APHIS) of the USDA.

The Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (FIFRA), as amended, authorizes the Environmental Protection Agency (EPA) to provide regulations concerning the development, movement, and use of pesticides, which by definition includes the development and utilization of microbial pesticide products; these include plant pathogens for biological control of weeds. ARS scientists are required to have knowledge of and adhere to those EPA regulations involving microbial organisms of both foreign and domestic origin which apply to development of microbials for weed control. EPA guidelines for microbial pesticides appear in 40 CFR Part 158 Subpart M, Part A "Microbial Pest Control Agents." Note: Those guidelines do not cover importation or interstate movement of agents.

The determination of the adequacy of quarantine/containment facilities for receipt and laboratory testing of foreign organisms, and of the technical competence of investigators, is the responsibility of APHIS-PPQ and pertinent State Departments of Agriculture. Determining the requirements that must be met for introduction of such organisms into or removal from containment and into the field is also their responsibility. An interdepartmental perspective for plans to contain (study) or release pathogens for biological control of weeds is provided to scientists and to APHIS by the Technical Advisory Group on the Introduction of Biological Control Agents of Weeds (TAGIBCAW). APHIS, through TAGIBCAW and other organizations, wants to assure that considerations of safety described in these Guidelines are made prior to the importation or field release of foreign biological control organisms into the United States. [NOTE: THE FOLLOWING STATEMENT CONTAINS A PROPOSAL AND IS RETAINED PENDING ACTION BY ARS, APHIS, AND OTHER AGENCIES.] Also, an interagency Biological Control Advisory Committee (BCAC) has been (proposed to be) established to provide technical support and advice to APHIS and researchers, upon request, on proposed importations and releases in the United States. [CLOSE OF STATEMENT]

Some of the below listed safety considerations can be made during the overseas exploration phases of a biological control introduction program, i.e., before importation of the proposed biological control agent, while others can be made during the domestic quarantine/containment phase of the introduction program. The procedures detailed in these Guidelines are designed to assure that such considerations are made and necessary precautions are taken.

The following references are recommended: Wapshere (1974, 1975, 1989); Charudattan and Walker (1982); Klingman and Coulson (1982-83); Lima (1983); Coulson and Soper (1989); Harris (1990); Way (1990); Howarth (1991); and Fisher and Andres (in press).

Major considerations for the importation and release of foreign microbial pathogens for control of weeds can be summarized as follows:

- 1) Prior to initiation of a biological control of weeds program, determination must be made of the weediness of the plant targeted for biological control and of any potential conflicts of interest in regard to that plant. See Section III.A.
- 2) Whenever overseas facilities and personnel permit, identification of the weed pathogens and preliminary host range studies will be made before shipment of exotic pathogens to the U.S. Otherwise, such studies will be conducted at PPQ- and State-approved quarantine/containment facilities. See Section III.A-B.
- 3) All foreign organisms shipped to the United States or later shipped interstate must be shipped in containers meeting USDA standards, and must be shipped under APHIS permit. See Sections III.B-C and V.C.
- 4) Exotic plant pathogens for biological control, with few exceptions, must be received in quarantine/containment facilities approved by APHIS-PPQ and pertinent State officials. This includes organisms that require testing prior to consignment or field release, or where potentially hazardous material is expected with shipments. See Section IV.A-C and V.A.
- 5) All testing of exotic pathogens must be conducted under strict quarantine conditions, where all material deemed to be of potential hazard or detriment is to be destroyed. A trained Quarantine Officer will be duly appointed who will be responsible for all quarantine operations. See Sections IV.C.
- 6) Authoritative identifications of the microbial organisms and of their host plants are required prior to their release or consignment from quarantine. See Section V.A.
- 7) Consignment of a pathogen to another PPQ-approved containment facility requires proper PPQ and State approval. See Section V.A-C.
- 8) Consideration must be made of all safety measures listed below prior to release or consignment of the pathogen material from quarantine/containment. See Section V.A-C.
- 9) Safety considerations and the potential impact on nontarget organisms must be described prior to field release of the organism. See Sections II.B and V.A-C.
- 10) Determination of "native" pathogens of the target weed or close relatives present in the proposed field release site prior to release of exotic microbes is recommended. See Section V.C.
- 11) Research results and proposals for importations or releases of biological control agents must be reviewed by an interagency review group. Proposals for field releases must be also reviewed by Canadian and Mexican officials. See Sections III.B and V.A-C.

12) Field releases from quarantine must be approved by APHIS-PPQ and pertinent State agencies. See Section V.C.

13) Voucher specimens are required of exotic organisms used in field releases, and APHIS and other officials are to be informed of all releases and shipments by proper documentation procedures and correspondence. See Sections III.D, IV.D, and V.D-E.

14) PPQ permit procedures and quarantine requirements, including state and local requirements that may apply, are to be followed for interstate shipment or export of weed pathogens. This does not refer to registered commercial microbial pesticide products. See Sections V.C.3, VI and VII.

B. Safety Considerations Required for Importation and Field Release of Foreign Pathogens for Biological Control of Weeds in the United States.

The following safety considerations, discussed further throughout these Guidelines, must be evaluated prior to considering the importation or release of foreign pathogens for biological control of weeds into the United States:

1. Protection Against Entry of Undesirable Plant Pathogens or Weeds.

a. Investigations must be made to determine whether a potential conflict of interest exists as to the weediness of the plant proposed for biological control; if any such conflicts cannot be resolved, such plants shall not be targeted for biological control by the use of introduced foreign invertebrate organisms.

b. Whenever overseas facilities and personnel permit, identification of the weed pathogens and preliminary host range studies will be made before shipment of the pathogens to the U.S.

c. Entry of host plant material must be restricted as much as possible; if entry of plant material is required, it must be destroyed in quarantine upon receipt.

d. Provisions are required for the elimination of all contaminants or secondary organisms, and for screening candidate pathogens for hyperparasites.

e. See item 4a below.

2. Protection Against Entry of Invertebrate Plant Pests.

a. Entry of exotic invertebrate material must be restricted as much as possible; contaminant invertebrates must be destroyed in quarantine upon receipt.

b. If entry of such organisms is required (e.g., for study as vectors), special permits must be obtained, special facilities are required (see Guidelines for weed arthropods), and they must be destroyed in quarantine as soon as possible.

3. Protection Against Entry of Weed Pathogens Hazardous or Nuisances to Humans or Domestic Animals.

a. Knowledge is required that the biological control agent will not induce infection on humans or animals. The potential for allergic reactions is also to be assessed, to insure that the pathogen does not have potential as a major common allergen.

4. Protection Against Entry of Pathogens Inimical to Native or Other Introduced Non-Target Organisms.

a. The potential effect of the biological control agent on non-target organisms, e.g., native plants of economic and ecologic value, endangered and threatened plant species, etc., must be considered; host specificity studies are required.

b. See also 1d above.

The degree of risk involved as to potential detrimental effects of a plant pathogen for biological control of a weed that may also attack non-target organisms (as in 3 and 4 above) should be weighed against its potential beneficial effects. Information from literature and field studies in the country of origin should be considered in concert with relevant laboratory tests.

III. Initial Importation of Foreign Pathogens for Biological Control of Weeds.

Precautions described in these Guidelines are for the safe shipment and receipt of all exotic weed pathogens, regardless of the amount of preliminary information. If possible, information on taxonomy, identification, and biology of the pathogen and its host(s) should be gathered from the literature and overseas field observations. Also, preliminary studies should be conducted, if possible, to assess the safety (host range) and potential usefulness of the candidate biological control agent in its native range.

After preliminary considerations, including determining the suitability of a plant as a biological control target as may be needed, and any overseas studies as may be possible, all exotic pathogens shipped to the U.S. for evaluation as biological control of weeds agents must: 1) have appropriate APHIS-PPQ shipping permit labels affixed to the outside of the packages; 2) be shipped in suitable containers; 3) be accompanied by specified documentation; and 4) be routed to and opened in designated approved primary quarantine facilities (see Section IV), with certain exceptions.

Inclusion of host plant, extraneous invertebrate material, or soil in shipments from foreign sources will be limited to those cases in which such inclusion is a necessity. Should unsolicited shipments of potentially useful organisms and/or host material not covered by APHIS permits or authority be received in quarantine, APHIS-PPQ should be notified immediately for post-shipment approval.

A. Initial Considerations.

1. New Plant Species Proposed for Biological Control.

If a plant species is newly proposed as a target of a biological control program involving the introduction of foreign control agents, a proposal to this effect must be made to the Technical Advisory Group on Introduction of Biological Control Agents of Weeds (TAGIBCAW). See Attachment 1 for the charter of the TAGIBCAW and a list of its organizational members. For ARS researchers, this proposal must first be submitted to the USDA-ARS National Program Staff (NPS) for preliminary approval.

The proposal should include the following information:

a. Biological factors:

- (1) Identification of the candidate weed, including full scientific name, classification, and sufficient characterization to allow unambiguous recognition.
- (2) Geographical distribution of the candidate weed, including information on probable area(s) of origin and any knowledge of the existence of various strains of the plant.
- (3) Digest of the known ecology and biology of the candidate weed including growth characteristics and documentation of its weediness.
- (4) History of the candidate weed since its introduction to the North American continent.
- (5) History of the candidate weed in other countries where it was introduced.

b. Economic factors:

- (1) Estimation of the current type and level of damage caused.
- (2) Costs of alternative control measures, including frequency of operations needed.
- (3) Forecast of the likely future extent of the problem based on the rate of expansion, if no action is taken.
- (4) Beneficial values or uses of the candidate weed in the U.S., Canada, Mexico, or Central America, or any information that the candidate is valued by a part of the community.
- (5) Comparison of the competition pressure of the candidate weed versus the potential pressure of introduced natural enemies on native species.

c. Potential control factors:

- (1) List of any records of natural enemies, highlighting species or groups likely to be good candidate biological control agents.
- (2) Biological control results achieved on any plant species related to the candidate weed.
- (3) Preliminary list of proposed plants to be included in host specificity studies.

The TAGIBCAW will provide the proposer with comments on the importance of the weed and whether a conflict of interest over its control may exist in North America. If a potential conflict of interest does exist, the TAGIBCAW and/or APHIS-PPQ will advise as to the type of data that might be required to resolve the conflict, or if the conflict is deemed insurmountable, the TAGIBCAW will so indicate and APHIS-PPQ may deny approval of the proposed program. The TAGIBCAW will indicate what considerations must be given to other plant species during the testing phase of an approved program to establish specificity and safety of proposed biological control agents.

2. Overseas Studies.

APHIS-PPQ approvals can be given for the importation into strict quarantine of unidentified and untested living pathogens for biological control of weeds. However, identification of the organism and preliminary host specificity and other tests sufficient to indicate the probable safety of the organism should be performed at overseas locations to the extent possible. In all cases, ARS researchers conducting such studies at overseas locations are responsible for knowledge of and adherence to the quarantine regulations of the country where tests are to be conducted. These pertain to the entry and use of exotic test plant species, exotic microbial agents, and associated materials.

B. Approvals, Permits, and Shipment Labels for Importation.

1. APHIS-PPQ Permits.

APHIS-PPQ permits and shipment labels are required for shipments of weed pathogens from foreign areas. Requests for permits and labels shall be made by the intended recipient by completion of Section A of PPQ Form 526 (Attachment 2). Supplies of PPQ Form 526 permit applications are available from APHIS-PPQ or ARS-BCDC. Particularly important information to be included on this form are indications of any expected host or soil material to be included in the shipments, if any, and the quarantine facility to which the shipments are to be sent.

The application (PPQ Form 526) should be sent, with an explanatory letter, to the regulatory official of the State in which the quarantine receiving facility is located, with a request that Section B of the form be completed and the form and explanatory letter be forwarded to APHIS-PPQ. PPQ will either issue a permit for the importation, deny the request, or request additional information prior to making a decision.

The permit consists of the completed PPQ Form 526 that indicates PPQ approval and any special restrictions or other stipulations in Section C of the form. If importation is approved, PPQ will send the permit to the applicant, with copies to the appropriate Quarantine Facility and State regulatory official and to the BCDC. PPQ will also send appropriate shipment permit labels to the applicant for forwarding to the shipper. The shipment label should be placed on the outside of each shipment package; it facilitates passage of the shipment through the mails or customs. The shipment label indicates PPQ approval of the shipment. Permits and shipment labels are valid for receipt and processing (evaluating) accessions/shipments in quarantine facilities for up to two years.

It is advisable to make arrangements with the designated Quarantine Facility prior to shipment. Details regarding number of acquisitions, special requirements for handling the material, and studies planned should be provided well in advance of intended importations, if known.

A list of approved quarantine receiving facilities for foreign weed pathogens is provided in Attachment 3. A list of the addresses and telephone numbers of State regulatory officials is provided in Attachment 4. Procedures for obtaining approval for interstate shipments from quarantine facilities and for field release of biological control agents for weeds are described in Section V of these Guidelines.

2. Initial Shipments to Non-Quarantine Facilities.

Requirement for initial U.S. receipt of weed biocontrol agents at an approved primary quarantine facility may be waived in some cases for shipments entering the United States from Canada. This requirement also may be waived in the case of some subsequent shipments from Canada. Special **proposed** guidelines for importations from Canada are described in Attachment 5, and similar guidelines may be applicable in the case of importations of weed biological control agents from Mexico. APHIS-PPQ permits are required in all cases.

C. Shipping Containers for Importation.

Exotic pathogens for shipment to primary quarantine centers must be packaged in appropriate containers that: 1) provide a suitable environment for the living organism(s), and 2) are strong enough to withstand the rigors of international shipment. A double container (package within a package) is usually adequate for most shipments, and provision within the container (cooling, aeration, padding, etc.) should be made that provides conditions to keep the pathogen(s) alive. The design of the package is dependent on the organism(s) shipped, and it will vary from shipment to shipment.

D. Documentation of Importation.

All shipments from foreign or overseas sources, or shipments from domestic sources that require quarantine receipt, shall be accompanied by an AD Form 944 (Attachment 6), with Section I of the form completed in accordance with instructions on the form. This **proposed** form provides source, culture, and other information for the recipient of the shipment, and feedback information for the shipper on the results of the shipment. All ARS and other overseas laboratories and personnel engaged in shipping microbial biological control agents to the United States, and all approved domestic ARS receiving facilities for exotic weed pathogens, will be provided by the BCDC with a supply of these forms, and the forms will be issued by them or by BCDC to explorers or other overseas shippers when notified by PPQ of the issuance of an importation permit or shipment labels for individual shipments. In cases where shipments are received without AD-944 type documentation, the receiving Quarantine Facility will be responsible for completion of Section I of the AD-944 form with information to be obtained from the shipper or other sources.

Whenever possible, ARS collectors and shippers should retain properly preserved specimens of the pathogens shipped and of their hosts, to serve as voucher specimens. Collectors and shippers should provide receiving facilities and the BCDC with information regarding the identity of the pathogens shipped and/or their hosts that may in time differ from that given originally on the AD-944 form.

See Sections IV.D and V of these Guidelines for more information concerning documentation procedures upon shipment receipt and voucher specimens.

IV. Quarantine (Containment) Facilities, Personnel, and Operational Procedures.

All ARS facilities charged with responsibility for the quarantine receipt and clearance in the United States of foreign pathogens for biological control of weeds must conform to certain required physical qualifications. [NOTE: THE FOLLOWING STATEMENTS ARE RETAINED PENDING DECISIONS BY ARS AND APHIS.] The facility must operate under a Compliance Agreement or Memorandum of Agreement between ARS, APHIS-PPQ, and pertinent State quarantine regulatory agencies. The Compliance Agreement, which will be monitored by APHIS-PPQ, will stipulate certain operational and documentation procedures required for operation of the facility in the quarantine receipt and handling, and transshipment and field release, of foreign pathogens for biological control of weeds. [CLOSE OF STATEMENTS]

A. Type of Facilities Required for Quarantine Receipt of Foreign Pathogens for Biological Control of Weeds.

All ARS facilities to be engaged in quarantine receipt of foreign pathogens for biological control of weeds are required to be inspected and approved for such purposes by authorized representatives of APHIS-PPQ prior to initiation of a Compliance Agreement or Memorandum of Agreement authorizing such operations. The inspection will be conducted to insure that adequate physical safeguards exist to minimize or eliminate the possibility of escape or accidental release of pathogens from the Quarantine Facility.

These physical safeguards, which will vary depending upon the type of organisms to be received, shall include:

[PHYSICAL QUARANTINE FACILITY REQUIREMENTS FOR INITIAL RECEIPT AND STUDY OF EXOTIC PLANT PATHOGENS FOR BIOLOGICAL CONTROL OF WEEDS NEED TO BE DEVELOPED BY A SCIENTIFIC PANEL. THE FOLLOWING ARE EXAMPLES ONLY.]

1) A double-door anteroom entryway with doors of arthropod escape-proof design (with gaskets to form a seal at all door edges, frame, and floor), and both equipped with automatic closers or electrical interlocking devices; first door locked at all times; a warning sign outside of first entry door stating "Quarantine Area-Only Authorized Personnel Permitted Entry."

2) Sealed or otherwise arthropod- and rodent-proof floors, walls, ceilings, windows and doors; all pipes, conduits, etc., penetrating ceiling, walls, or floors, must be carefully sealed with silicon caulking at both inside and outside surfaces; in anteroom, use black paint for walls, doors, and ceilings; for walls in rest of quarantine use white, epoxy paint, gray for floors; windows, if any, must be triple-glazed and shatter proof.

- 3) Sealed or otherwise insect- and mite-proof electrical system, including sealed floor and wall plugs, switches and lights.
 - 4) Closed air systems for heating, cooling, and exhaust, fitted with filters adequate to prevent escape of insects, mites, and pathogens. A pressurized air system, with positive pressure in non-containment areas and negative pressures in containment areas, is mandatory.
 - 5) Plumbing system designed to prevent escape of insects, mites, and pathogens, including adequate screening of floor drains and other accessible drain lines. A trap where waste water from the Quarantine Facility can be sterilized or otherwise treated is mandatory.
 - 6) Direct access in quarantine to incineration or heat treatment systems for destruction or sterilization purposes.
 - 7) Traps effective for various arthropod species placed in anterooms and any other strategic possible escape routes.
 - 8) Provision for maximum security area for initial opening of incoming packages of exotic material.
 - 9) Intercommunication system to allow communication with quarantine personnel without need to enter or leave quarantine area.
 - 10) Sealed emergency door with panic hardware, wired to an alarm, with sign "Emergency Exit Only;" fire warning alarms in quarantine.
 - 11) One or more quarantine greenhouse bays for the conduct of host specificity and other biological studies; each bay must have separate air handlers, appropriate filters, concrete floors and foundations, air tightness, safety glass, hail damage protection, negative pressure, and a sterilizer.
 - 12) Provision for fumigation of plant materials entering quarantine areas; preferably a pass-through autoclave, with interlocking doors that prevent inner and outer doors opening at same time.
 - 13) Provision for shower room and/or for change of clothing in quarantine area.
- [END OF LIST OF EXAMPLES]

B. Approval of Quarantine Facilities.

1. Inspection and APHIS Approval.

If physical safeguards are deemed to be adequate after inspection by APHIS-PPQ, or following the rectification of any deficiencies found during inspection, APHIS will issue a dated and renewable certificate indicating approval for operation of the facility as a primary receiving center for foreign weed pathogens. This certificate should be prominently displayed by the approved facility. APHIS officials will conduct unannounced re-inspections of the facility to assure the continuing adequacy of these physical safeguards. State regulatory officials are also authorized to inspect the facilities upon their request.

ARS and other facilities currently authorized to serve as quarantine facilities for initial receipt of weed pathogens are listed in Attachment 3. No other ARS facilities are authorized to receive weed pathogens directly from foreign sources, with some exceptions as authorized by PPQ (see Section III.A.3). As the safety of the foreign pathogen is determined and appropriate approvals are obtained, the pathogen may be consigned to other quarantine containment facilities for further research; such ARS facilities proposed to be approved for such studies are also listed in Attachment 3. [ATTACHMENT TO BE PREPARED]

The approved ARS quarantine receiving facilities will provide address labels and pertinent shipping instructions, including instructions to airline, post office, and customs officials as appropriate, to ARS and other overseas laboratories and personnel upon request, or to the permittee (applicant) upon notification of issuance of a permit for shipment to be received at those facilities (see Section III.B).

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY ARS AND APHIS.]

2. Compliance Agreements or Memoranda of Agreement.

As noted in these Guidelines, ARS quarantine facilities will be required to operate under a Compliance Agreement or Memorandum of Agreement between ARS, APHIS-PPQ, and pertinent State quarantine regulatory agencies. The specific provisions of these Compliance Agreements or Memoranda of Agreement authorizing Quarantine Facility operations, which will vary depending on the location and type of each facility, will be determined by APHIS-PPQ in consultation with pertinent State regulatory officials and ARS line and staff officials and research personnel. These provisions will include:

- 1) Approval of the physical safeguards of the Quarantine Facility, as discussed in Section IV.A. above.
- 2) Agreement for Quarantine Facility adherence to quarantine importation permit procedures as outlined in Section III.A-B of these Guidelines (insofar as Quarantine Facility involvement in such procedures is concerned), and for adherence to transshipment and release procedures as may be agreed upon, as outlined in Section V of these Guidelines.
- 3) Approval of specific quarantine operational procedures for the Quarantine Facility, as summarized in Section IV.C of these Guidelines, including safety considerations and precautions to be made in quarantine handling and clearance for release from quarantine of foreign pathogens for weed control as discussed in Section V of these Guidelines.
- 4) Agreement for Quarantine Facility compliance with documentation procedures to be agreed upon, as outlined in Sections III.D, IV.D, and V.D-E of these Guidelines.
- 5) Any other specific procedures or regulations to be followed, or specific restrictions on types of materials to be received or shipped, as may be required by regulatory agencies of the State in which the Quarantine Facility is located.
- 6) Designation of a Quarantine Officer for the Quarantine Facility responsible for assuring compliance as noted in items 2-5-above.

These Compliance Agreements or Memoranda of Agreement must be approved by the appropriate ARS and APHIS-PPQ officials, and the pertinent State regulatory agency, and will be monitored by APHIS-PPQ officials to the extent they may deem necessary. State regulatory officials are also authorized involvement in monitoring of these agreements.

[END OF RETAINED SECTION]

C. Quarantine Personnel and Operational Procedures.

1. Quarantine Personnel.

Each Biological Control Quarantine/Containment Facility will have a designated Quarantine or Containment Officer. Quarantine Officers will be appointed by the appropriate ARS official after consultation with the NPS, Research Leaders or Laboratory Chiefs, and Area or Center Directors. The Quarantine Officer will be thoroughly trained in quarantine philosophy and quarantine operational procedures, and will be responsible for assuring that these procedures are followed. Specific responsibilities include:

- a) Adherence to permit, documentation, voucher, and other specifically required procedures;
- b) Proper confinement of all organisms in the quarantine areas;
- c) Handling of these organisms, by himself or any worker assigned to the quarantine program, in a manner to prevent escape of organisms;
- d) Obtaining authoritative identification of the organisms;
- e) Authorizing the release of organisms from quarantine after screening; and
- f) Packaging and shipment of organisms in such a manner as to prevent their escape during transport.

Ultimate responsibility for the release of organisms from the Quarantine Facility rests with the Research Leader of the facility, who in certain cases may himself be designated Quarantine Officer.

Other personnel assigned to the quarantine program will be limited in number, and thoroughly instructed in the quarantine operational procedures (QOP). A list of personnel authorized access to the quarantine area will be prepared and prominently posted. All other personnel will be denied access to the quarantine areas unless accompanied by the Quarantine Officer or his designated representative.

2. Quarantine Operational Procedures (QOP).

Each ARS Biological Control Quarantine (or Containment) Facility will prepare specialized Quarantine Operational Procedures (QOP), which may differ depending on the location, primary mission, physical construction, and staffing of the facility. These operational procedures will be approved by appropriate ARS line and staff officials, and by APHIS and State regulatory officials before authorizing operation of the facility as a Quarantine Facility for receipt of foreign microbial biological control agents for weeds. The approved QOP will be posted near the entrance of the quarantine/containment area of the facility. APHIS officials will conduct periodic unannounced inspections of the facility to ascertain that these procedures are being followed, and State regulatory officials may also conduct such inspections.

Operational procedures must include:

- a) Permit and approval procedures for importations (see Section III.B), including provision for handling unsolicited shipments arriving without proper permits or approvals, and for following other specific procedures as may be stipulated in the importation permit.

- b) Provisions for assuring maintenance of quarantine/containment conditions, including limited access to containment areas, and requirements for protective clothing, etc.
- c) Provision for opening of incoming shipments only in special containment areas within the main quarantine area.
- d) Description of means of destruction or sterilization of shipping containers and packing material within quarantine.
- e) Means to quarantine imported material and to eliminate inadvertently, inappropriately, or necessarily included organisms, such as exotic plant material and contaminants. If at all possible, only healthy domestic host material will be used if required to maintain cultures of pathogens in quarantine.
- f) Means for obtaining rapid authoritative identification of pathogen species received in quarantine, to the extent as may be required.
- g) Detailed protocol to be followed prior to release of organisms from maximum quarantine containment area for further testing as required, or prior to the decision to release organisms from quarantine for further shipment or field release. This protocol should include consideration of the known or tested host range and relationships of the species or of the taxonomic group to which it belongs, its potential effect on other beneficial organisms, adequacy of safeguards for elimination of contaminants, adequacy of taxonomic identifications, and other safety considerations listed in Section II.B of these Guidelines. See also Section V of these Guidelines.
- h) Means for quarantine storage of the imported pathogens.
- i) Shipping procedures, including proper packaging, and documentation procedures (see Section V.C of these Guidelines).
- j) Documentation procedures (see Sections III.D, IV.C, and V.D of these Guidelines).
- k) Voucher procedures (see Section V.E of these Guidelines).
- l) Provisions for monitoring of the QOP by the Research Leader or Laboratory Chief of the Quarantine Facility.

D. Documentation of Receipt of Imported Material.

The Quarantine Officer of each approved ARS weed pathogen receiving quarantine/consignment facility is responsible for completion of Section II of **proposed** AD Form 944 (Attachment 6), which is to accompany each shipment of foreign material received (see Section III.D of these Guidelines), and for filing and distribution of the copies of this form according to instructions on the form. The Quarantine Officer is also responsible for assuring that these forms are included in all incoming shipments, or for their preparation if not so included.

A record of all shipments and species received in the receiving facility will be periodically provided to ARS-BCDC, APHIS-PPQ, and the pertinent State regulatory agency, as may be stipulated in the importation permit. (See also Section V.D for additional records to be provided by the receiving facility).

The Quarantine Officer should retain properly preserved specimens of incoming material, and of original host material, if available, to serve as vouchers representing material received in quarantine. See Section V.E for additional information concerning voucher specimens.

V. Release of Foreign Microbial Biological Control Agents for Weeds from Quarantine/Containment.

The ultimate responsibility for the release/consignment of an organism from quarantine rests with the Research Leader or Laboratory Chief of the ARS Quarantine Facility, although authority for making this decision may be delegated to a designated Quarantine Officer under certain circumstances. Procedures and considerations required prior to release from quarantine are included in the facility's QOP [FOLLOWING PHRASE IS RETAINED PENDING ARS AND APHIS DECISIONS.] and Compliance Agreement or Memorandum of Agreement [END OF PHRASE] approved by APHIS (see Sections IV.B-C and V.A-E of these Guidelines). The Quarantine Officer is responsible for: 1) Assurance that safety considerations (see Section II.B) are made prior to release/consignment of the organism from quarantine, or that proper arrangements are made for any additional testing deemed to be required; 2) Assurance that any necessary authorizations for field release and/or interstate shipment of the organism are obtained, which involves review of research information by TAGIBCAW, State and Federal officials, and possibly others, and APHIS-PPQ permits; 3) Documentation procedures involved following release from quarantine; and 4) Retention of voucher specimens as appropriate.

A. Safety Considerations and Testing, and Quarantine Clearance.

Included in the QOP, [FOLLOWING PHRASE RETAINED PENDING ARS AND APHIS DECISIONS.] which are an integral part of the Compliance Agreement or Memorandum of Agreement to be entered into between the ARS Quarantine Facility, APHIS, and the pertinent State regulatory agency, [END OF PHRASE] are detailed protocols to be followed prior to release of organisms from quarantine (see Section IV.C.2.g). These protocols include in-house review, clearance, and testing procedures, and obtaining recommendations from the TAGIBCAW and permits further review as may be necessary, and application for permits from APHIS-PPQ, which involves the preparation of an Environmental Assessment for initial U.S. field release of plant pathogens for biological control of weeds.

1. Review and Clearance Procedures.

The Quarantine Officer and scientists involved with evaluations will review and summarize all available information about the biological control agent proposed for clearance. This includes data on ecology, biology, and taxonomy of the species, information from discussions with experts, and a summary of data from previous and current (containment) studies regarding safety of the organism (Section II, III.B). Reliable identification of the organism is required, and live material for which there is insufficient data on taxonomic or host relationships will not be permitted to leave quarantine. During these studies and for later review, special attention will be given to the four areas of safety (Section II.B). Based on reviews, research, and discussions, a conclusion is reached by the Quarantine Officer, pertinent researchers and regulatory officials as to whether or not the identified organism worthy of further evaluation. The identified organism is assigned to one of two extremes of the four quarantine categories:

Class A: The organism is considered dangerous or otherwise unsuited for continued experimentation. All material placed in this category must be destroyed in quarantine.

Class D: The organism is considered safe for field release in the U.S. Material placed in this category will require additional review as described in Section V.B below, prior to being field released or shipped interstate.

2. Quarantine Testing.

Among the safety considerations (Section II.B) is the need for information that may require testing of the organism under quarantine conditions. Tests are required to a) determine the extent of potential damage to non-target plants, b) determine the potential host range of the pathogen, and c) assure the elimination of foreign plant pathogen contaminants. Information on organizing a host range study can be found in Wapshere (1974). Host specificity evaluations need to include provisions to ascertain whether plant species on Federal or pertinent State lists of rare or endangered species will be further endangered by the weed natural enemy proposed for introduction. This may involve testing of surrogate species closely related to those listed, if propagative material of related rare or endangered species can not be obtained for study.

Tests may also be deemed desirable to determine whether the potential natural enemy is capable of causing significant harm to or allergic reactions in humans or domestic animals and the likely extent of such action. In these cases, which may be rare, FIFRA testing guidelines may need to be followed (see 40 CFR Part 158 Subdivision M, Part A "Microbial Pest Control Agents.").

If, following quarantine testing of the organism, any doubt remains concerning the propriety of release/consignment of the organism from quarantine, the matter may be placed before an *ad hoc* panel of scientists [PHRASE RETAINED PENDING ARS AND APHIS DECISIONS.] and/or the BCAC (see Section V.C) [END OF PHRASE] for arbitration.

B. Approval and Permits for Field Release or Interstate Shipment of Foreign Microbial Biological Control Agents for Weeds.

1. General Requirements.

Specific approval procedures for consignment from quarantine, field release, and/or interstate shipment of foreign microbial biological control agents for weeds will be stated in the facility's QOP [PHRASE RETAINED PENDING ARS AND APHIS DECISIONS.] and Compliance Agreements or Memoranda of Agreement between the involved Quarantine Facilities, APHIS, and State regulatory agencies. [END OF PHRASE]

In general, these approval procedures will include:

a. A requirement for specific authorization from APHIS-PPQ for the initial field release of an exotic species in the United States, which in turn requires (1) preparation by the researcher of a document containing information for an Environmental Assessment (EA) and a review of research for review by TAGIBCAW, PPQ, State regulatory agencies, [PENDING DECISIONS] ARS and/or BCAC, and (2) approval of the State in which the release is intended;

- b. Notification of EPA for field studies involving less than 10 acres (or less than one acre of water), or receipt of an Experimental Use Permit (EUP) for larger field studies from the EPA;
- c. A requirement for State approval and an APHIS-PPQ permit for all interstate shipments of these organisms;
- d. Proper documentation of all shipments and field releases for APHIS-PPQ, ARS-BCDC, and pertinent State agencies; and
- e. Adequate packaging to prevent escape of organisms during transit.

The Quarantine Officer is responsible for adherence to these procedures. All applications for State approvals or APHIS permits for field release or interstate shipment shall be initiated by use of PPQ Form 526 (Attachment 2).

2. Field Release by Quarantine Facilities.

- a. Federal and State regulations.

Before a new candidate foreign biological control agent can be field released or shipped interstate from quarantine, provisions must be made to meet the requirements of certain Federal and State regulations impacting the introduction of exotic organisms for biological control of pests. The Federal regulations involved, in addition to the Plant Quarantine Act (PQA) and Federal Plant Pest Act (FPPA) already mentioned in these Guidelines as regulating the importation and movement of live organisms, include the following: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the National Environmental Policy Act (NEPA); and the Endangered Species Act (ESA). The ARS Research Leader, Quarantine Officer, and involved researcher, are responsible for adherence to the requirements of regulations under these Acts as noted below.

FIFRA: Under this Act, which is administered by the Environmental Protection Agency (EPA), all biological agents used for control of pests are classified as pesticides, and thus their movement and use is regulated by EPA. EPA has exempted from regulation under FIFRA invertebrate biological control organisms on the grounds that they are adequately regulated by the USDA, primarily by APHIS under the PQA and FPPA and associated regulations. However, EPA regulations under FIFRA must be followed in the development of microbial pesticides.

NEPA: Under this Act, all Federal or Federally-supported agencies must consider the environmental impact of major actions that may significantly affect the quality of the human environment in the U.S. USDA agencies interpret this to mean that, with certain exceptions, an Environmental Assessment (EA) is required for the initial field release of exotic biological control agents in the U.S. That is, an environmental risk analysis must be applied in such actions by ARS (ARS, 1986), and for the issuance of Federal permits by APHIS for the initial field release of introduced plant pests or potential plant pests. No foreign microbial natural enemy of weeds is exempt from this requirement, since these are all potential plant pests and must be shown to have no detrimental effects on the quality of the environment.

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTIONS BY ARS AND APHIS.] For initial release of organisms not exempted from a formal EA requirement, environmental assessment protocol documents have been prepared, the complexity of which vary with the level of risk involved. Attachment 7 presents a format or protocol for providing information required for developing an EA required prior to issuance of a permit for initial release of non-exempted organisms. In cases where the level of risk is considered to be high, an Environmental Impact Statement (EIS) would be required. See section b below for the roles of the TAGIBCAW and BCAC in these procedures. [END OF RETAINED SECTION]

ESA: This Act, administered by the Fish and Wildlife Service (FWS) of the USDI, concerns the impact of Federal actions on native endangered and threatened animals (including arthropods) and plants in the U.S. Some of the safety evaluations noted in Sections II.B. and V.A are designed to meet these concerns. Comments on these concerns and results of any test results related to them should be noted on the permit application or EA protocol document.

Several States have laws and regulations regarding environmental policy and/or endangered species within their boundaries, similar to NEPA and ESA. In addition, certain States have regulations requiring permits or approval prior to shipment or release of live foreign organisms within their borders, or have otherwise formally requested notification prior to such importations or releases (see Attachment 10). Knowledge of and adherence to pertinent State regulations are responsibilities of the involved ARS Quarantine Facility researcher, Research Leader, and Quarantine Officer, prior to the initial release of biological control organisms in the U.S.

- b. Procedures for obtaining authorization for initial releases of microbial biological control agents of weeds in the United States.

Prior to initial consignment from quarantine and/or field releases of newly-imported biological control agents for weed pests in the United States, documentary evidence of the pros and cons of the proposed release, including a review of the quarantine and other research results concerning the organism proposed for release, and the views of the researcher(s), must be prepared for review by the TAGIBCAW and also possibly by the BCAC. This report or petition must be prepared by the involved research worker, roughly following the format suggested by Klingman and Coulson (1982-83), if desired. An EA protocol document should also be prepared at the same time, following the format shown in Attachment 7. Both documents, or a single document combining the two formats, should be submitted to the TAGIBCAW Executive Secretary who will arrange for their review by the TAGIBCAW and by Canadian and Mexican quarantine officials; 20 copies of the document(s) are required for such reviews. The TAGIBCAW may (1) recommend approval of the proposed release with the documentation presented, (2) recommend against the proposed release, (3) request additional information and/or testing prior to making a decision, or (4) recommend that a formal Environmental Impact Assessment (EIS) be prepared [FOLLOWING PHRASES RETAINED PENDING DECISIONS BY ARS AND APHIS.] or that the matter be referred to the BCAC (see Section V.C) for consideration in order to obtain approval for the release. In the latter case, the researcher will submit all documentation already submitted to the TAGIBCAW, and additional

information as may be requested, to the BCAC Executive Secretary with a request for a formal review of the case. APHIS-PPQ may also request a detailed EA protocol document from the researcher and a formal review of the case by the BCAC. [END OF RETAINED SECTION]

Following a favorable recommendation by the TAGIBCAW, and/or BCAC, appropriate State approval(s) and an APHIS permit must be obtained, using PPQ Form 526, by the ARS Quarantine Facility or other facility proposing to make the initial release. Section A of PPQ Form 526 will be completed by the facility indicating the intent to field release the biological control agent in a specific State.

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY EITHER ARS OR APHIS OR BOTH.]

There are then two possible scenarios:

(1) An appropriate EA protocol document (see NEPA requirements above and Attachment 7), as may be amended after TAGIBCAW comments, will be prepared by the permit applicant and included with the appropriate permit application form when submitted to the State regulatory official in whose State the initial field release is intended. State approval will be indicated in Section B of the form, and the form will be forwarded by the State official to APHIS, where the document will receive an in-house review in APHIS, and/or by BCAC as may be requested. After a favorable review, APHIS will prepare an EA and, if this results in a Finding of No Significant Impact (FONSI), APHIS-PPQ will complete Section C of the permit application form. PPQ will return the completed form (which constitutes the permit) to the applicant, with copies to the involved Quarantine Facility (if this differs from that of the applicant), and to the BCDC and the pertinent State regulatory agency. The permits, valid for 3 years, may be renewed for another 3-year period, after which no further permits for release of the permitted organism in that State shall be required. The Quarantine Officer shall be responsible for permit renewals.

(2) For the second option, the ARS researcher proposing the initial U.S. field release of an introduced biological control agent will submit the appropriate EA protocol documents (see Attachments 10-12) to the pertinent ARS office for review. A FONSI will subsequently be prepared by ARS which will be then be included with the permit application form when sent to APHIS via the appropriate State regulatory agency. APHIS-PPQ may then issue the permit and send copies as in option 1.

The researcher, or APHIS, or the pertinent ARS office, will submit all appropriate environmental documents, and a copy of the APHIS-PPQ permit, to EPA, in order to comply with the current requirement of notification of EPA of field studies for microbial organisms involving less than 10 acres (or less than one acre for applications to be made to bodies of water); if the proposed release is to involve larger areas, procedures for obtaining an Experimental Use Permit (EUP) must be initiated, following EPA guidelines. [END OF RETAINED SECTIONS]

The ARS Research Leader has the responsibility of giving final approval for release after APHIS and State approvals are in hand, and notification of EPA. This is done by memo to the researcher, with copies to the overseas supplier of the organism, NPS, the BCDC, the concerned Area office, and potential cooperators.

- c. Subsequent releases of foreign microbial biological control agents for weeds.

Completion by the Quarantine Facility or other shipping/releasing facilities of Section A of the PPQ Form 526 for State regulatory agencies is also required for subsequent releases of the same organism in additional States. If the release is approved by the State in Section B, the PPQ Form 526 will be forwarded by the State official to APHIS-PPQ for completion of Section C. Based upon prior release approval and State recommendation, APHIS will distribute copies of the completed form (the permit) as above. The Quarantine Officer or pertinent personnel at other facilities will maintain a file of such State approvals and permits.

For certain releases in the State in which the Quarantine Facility is located of organisms already cleared for release, APHIS and State approval *may* be obtained on the same PPQ Form 526 used for requesting importation permits (see Section III.B), by indicating the intent to release on the form when first submitted.

After permits are obtained for their initial releases, no other prior action is required for subsequent field release of hand-carried microbial biological control of weeds agents in States approving their release, until expiration of the permit (generally 3 years), which must then be renewed. However, appropriate regulatory agencies in these and all other States in which releases are made shall routinely be informed periodically in writing of all releases made within their boundaries by ARS Quarantine Facility personnel. EPA, APHIS-PPQ, and ARS-BCDC shall also be similarly informed. The Quarantine Officer shall be responsible for such notification.

3. Interstate Shipment from Quarantine and Non-Quarantine Facilities Engaged in Receipt or Culture of Introduced Microbial Biological Control Agents for Weeds.

It may be occasionally deemed necessary for the imported weed pathogen to undergo certain tests at APHIS-PPQ-approved quarantine facilities other than that in which it was originally received, prior to completion of the requirements for field release. In these cases, special permits for the transfer of the foreign pathogen material between quarantine facilities must be obtained from APHIS-PPQ and the appropriate State official in the State receiving the material. There is no requirement for TAGIBCAW or BCAC involvement in these permit procedures.

After clearance for field release of the pathogen has been received, the material may be shipped to other facilities, quarantine or non-quarantine for propagation and/or field release. The intended recipient of the foreign material to be shipped through or otherwise received from ARS quarantine facilities, or from non-quarantine facilities, shall be responsible for obtaining State approvals and APHIS-PPQ permits for such interstate shipments. Such State approvals and APHIS-PPQ permits will be obtained using PPQ Form 526 in the same manner as such approvals or permits for field release are obtained by the Quarantine Facility (see Section V.B.2). The Quarantine Officer can assist the intended recipient in completion of Section A of the form, as may be required.

If the material is to be field released by the recipient, this intent must be clearly indicated on the PPQ form 526. If the release in the State is approved in Section B, the PPQ Form 526 will be forwarded to APHIS-PPQ by the State regulatory agency for issuance of a permit (completion of Section C of the form) and APHIS-PPQ will provide copies of the permit to the applicant, the Quarantine Facility or non-quarantine facility, BCDC, the State regulatory agency, and EPA. The Quarantine Officer or pertinent non-quarantine personnel will maintain a file of such permits, and provide.

Arrangements for State approvals and/or APHIS permits must be made well in advance of intended shipments, to prevent the loss of valuable live materials while awaiting approval procedures.

All foreign microbial biological control agents shipped from ARS quarantine facilities will: a) be packaged in containers designed to prevent escape of the organisms during transport (see Section III.C); b) have an APHIS-PPQ shipping permit label authorizing interstate shipment affixed to the outside of the package; and c) be accompanied by shipment record forms (see Section V.D).

No further action is required for interstate shipment or release of the permitted foreign microbial biological control agents, other than periodic permit renewal (see Section 2.c above). However, appropriate regulatory agencies in all States to which such shipments and releases have been made will routinely be informed periodically in writing of the recipients and contents of all shipments made to, and releases made in their States by ARS quarantine and pertinent non-quarantine facilities. APHIS and BCDC shall be similarly informed. The Quarantine Officer(s) shall be responsible for such notification for ARS quarantine facilities.

[THE FOLLOWING SECTION CONTAINS A PROPOSAL AND IS RETAINED PENDING DECISIONS AND ACTIONS BY ARS, APHIS, OR OTHER AGENCIES.]

C. Interagency Biological Control Advisory Committee (BCAC).

The BCAC is an interagency advisory group [proposed to be] established to provide technical support and advice to ARS and/or APHIS, upon request: (1) in evaluating risks with specific requests for permits to import or release exotic biological control agents; and (2) in establishing criteria for appropriate evaluation of requests for permits involving biological control organisms. The BCAC will not be involved in making regulatory decisions; it will be consulted regarding proposed importations and releases, primarily in regard to environmental safety factors, in cases in which Federal or State regulatory agencies seek further scientific input to make a regulatory decision, and can serve to resolve any substantive disagreements between APHIS and applicants, or upon specific appeal by biological control research workers, etc. See Attachment 9 for an outline of procedures involving BCAC for providing APHIS and/or ARS with such technical support, and Section V.B above for specific information in regard to its involvement in field releases of introduced biological control agents. All communications with BCAC should be addressed to its Executive Secretary.

After final review of information concerning microbial biological control agents assigned to Class D (see Section V.A.1), including information resulting from tests conducted in containment and other facilities, if any doubt remains as to the propriety of release of the pathogen from containment status, the question may be placed before BCAC for an informal review. This may be done by the

Quarantine/Containment Officer of the facility in which the tests were conducted, or by research workers at that or other facilities who are interested in obtaining clearance for such release. Documentary evidence pro and con will be accumulated for presentation to BCAC, together with an explanatory memo stating the position of the involved Quarantine/Containment Facility, and supportive or contradictory memoranda from interested research and regulatory officials. BCAC will respond with a consensus opinion indicating support or lack of support for the proposed action. If the consensus opinion is favorable, the Containment Facility can proceed with field release or interstate procedures, in which the BCAC may be more formally involved (see Section V.B).

[END OF RETAINED SECTION]

D. Documentation of Quarantine Consignments, and Quarantine and Non-Quarantine Shipments and/or Field Releases of Introduced Microbial Biological Control Agents for Weeds.

A photocopy of the original **proposed** AD Form 944 (Attachment 6) documenting initial importation of the foreign material should be included with all consignments and shipments of foreign pathogens made by ARS quarantine receiving facilities, with notes on any passages in hosts other than the original host. It is highly recommended that all other ARS researchers provide copies of the original AD Form 944 and similar notes for all subsequent shipments of the foreign pathogen material.

As noted in Sections IV.D and V.B above, ARS quarantine facilities approved for initial receipt of foreign pathogens will maintain a record of all shipments of these pathogens and provide a written record periodically: 1) to appropriate regulatory agencies in the State in which the quarantine facility is located, 2) to such agencies of all other States to which shipments have been made, 3) to APHIS, and 4) to BCDC. The Quarantine Officer(s) shall be responsible for such notification.

The field release of pathogens cleared for field release in accordance with procedures outlined in Section V.A-C should be documented by use of the **proposed** AD Form 944A (Attachment 10), following instructions on the form. A single AD Form 944A may be used to record multiple releases, noting a range of release dates in Section II of the form. This form provides source, culture, and other information to document the field release. Copies of the completed form should be sent to the pertinent ARS receiving facility, and to BCDC and APHIS-PPQ, and to EPA as may be requested.

All ARS quarantine facilities, and BCDC, will be provided with supplies of AD Form 944A and will provide, upon request, supplies of these forms to persons and facilities engaged in non-quarantine culture, shipment, and release activities.

The Quarantine Officer of each ARS pathogen quarantine facility shall be responsible for assuring proper documentation of consignments, shipments, and/or releases of foreign microbial biological control agents, using AD Forms 944 and 944A, and for distribution of the copies of the forms.

E. Voucher Specimens.

Retention of specimens representing imported and released material is required in some cases, and it is highly recommended in all cases. All material to serve as voucher should be retained, or sent, for inclusion in the exotic weed pathogen collection maintained in liquid nitrogen at the Foreign Disease - Weed Science Research Unit (FDWSRU), ARS, Frederick, MD. Taxonomic specimens of foreign fungal pathogens released for biological control of weeds should also be sent for inclusion in the National Fungal Collection of the Systematic Botany and Mycology Laboratory (SBML), Plant Sciences Institute, ARS, Beltsville, MD. This provides a permanent record of the importation and release of exotic organisms in the United States for immediate or future use by taxonomists and biological control researchers.

Of particular importance are voucher specimens to document:

- 1) The first field release in the United States of a foreign microbial biological control agent by quarantine or other facilities; these voucher specimens should include specimens from each major geographical area (at least from each country) of origin of the released material;
- 2) Subsequent field releases of the same species from new major geographical areas;
- 3) Field releases from long-established laboratory or storage cultures; and
- 4) The first additional field release of a newly imported foreign species if such releases are resumed after a period of three or more years after initial field release.
- 5) Retention of properly prepared and labeled herbarium specimens of the original host plant and of the plants included in the specificity tests, other than the common cultivated crop plants, is also highly recommended.

[GUIDELINES FOR PROPER PREPARATION AND STORAGE OF VOUCHER MATERIAL AND REQUIREMENTS FOR SHIPMENT OF MATERIALS FOR RETENTION AT FDWSRU AND SBML, ASSUMING THESE ARE TO SERVE AS THE SOLE REPOSITORIES FOR IMPORTED WEED PATHOGENS NEED TO BE PREPARED BY SCIENTIFIC PANEL OF ARS AND OTHER PLANT PATHOLOGISTS.]

VI. Interstate Shipment of Native or Naturalized Microbial Biological Control Agents for Weeds.

All ARS facilities and personnel engaged in the field-collection or laboratory culture of native or naturalized (i.e., established exotic) weed biological control agents for shipment to other States or U.S. Territories shall be responsible for ascertaining and adherence to quarantine and other requirements of the States or Territories to which the material is to be sent (see Attachments 4 and 8). State or Territorial approvals and APHIS-PPQ permits are required for such shipments. These approvals and permits shall be obtained by the intended recipients in the same manner as indicated in Section V.B.3 of these Guidelines. This Section does *not* refer to the shipment of commercial microbial pesticide products.

All ARS facilities engaged in interstate shipment of laboratory propagated or field-collected native or naturalized weed biological control agents for weeds will maintain a record of such shipments, including records of origin, dates of shipment, and recipients, and will provide such records to BCDC and APHIS-PPQ on an annual basis. State or Territorial regulatory agencies may also request annual notification of shipments made to facilities or personnel within their boundaries. The proposed AD Form 944

(Attachment 6) is available for use by ARS facilities for providing information to the recipient and obtaining feedback information, and for documenting the shipments and/or releases. However, this form need not be used, if a similarly detailed system of providing information and documenting shipments and releases of exotic microbial biological control agents is used and pertinent reports are made available to ARS-BCDC and APHIS-PPQ, and to State regulatory officials as may be requested.

VII. Export of Microbial Biological Control Agents for Weeds to Other Countries.

All ARS domestic and overseas facilities and personnel making shipments of microbial biological control agents for weeds to foreign countries for research purposes will determine whether or not quarantine regulations exist in the country to which the shipment are to be made, including any requirement for quarantine entry permits, and are responsible for adherence to those regulations, if any.

All shipments to foreign countries shall be shipped in containers designed to prevent escape of organisms. Host materials or soil will not be included in the shipments unless absolutely required, and unless specific approval for such inclusion is obtained from the foreign government.

[PARAGRAPH RETAINED PENDING DECISIONS BY ARS AND APHIS.] Although not legally required, it is highly recommended that an APHIS-PPQ shipping permit label (or equivalent ARS label to be developed) be affixed to the outside of the package near the address labels, together with the foreign permit label, if applicable. These shipping labels may be obtained from ARS-BCDC, who will issue the labels only after receipt of documentary evidence that all foreign quarantine regulations have been met or that there are no quarantine regulations (e.g., photocopies of permits or relevant correspondence).
[END OF RETAINED PARAGRAPH]

As a courtesy and for the information of the foreign recipient, an AD Form 944 shipment record form (Attachment 6), with Section I completed, should accompany each shipment, with a request that Section II of the proposed form be completed, and the form returned to the sender. The sender is responsible for distribution of copies of the form in accordance with instructions on the form.

Although no voucher specimens are required, it is highly recommended that the sender of shipments to foreign countries retain such specimens to document the contents of the shipments for possible future reference.

VIII. Recommended References.

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Attachment 1

Charter of the Technical Advisory Group on Introduction of Biological Control Agents of Weeds, and List of its Organizational Members

SEE NO. 17 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Attachment 2

PPQ Form 526: Application and Permit to Move Live Plant Pests or Noxious Weeds

SEE NO. 1 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Attachment 3

List of ARS Biological Control Quarantine/Containment Facilities **Proposed to be** Approved for Initial Receipt of Foreign Pathogens for Biological Control of Weeds

TO BE PREPARED

Attachment 4

List of Plant Regulatory Officials of U.S. States and Territories, Canada, and Mexico

SEE NO. 3 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Attachment 5

Proposed Guidelines for U.S. Importation of Exotic Natural Enemies of Weeds from Canada

SEE NO. 18 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Draft AD Form 944: Record of Shipment of Exotic Microorganisms for Biological Control

SEE NO. 19 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Biological Control Agents: Long Format

SEE NO. 11 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries

SEE NO. 13 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES
TO BE PREPARED

Proposed Structure and Procedures of the Proposed Biological Control Advisory Committee (BCAC)

SEE NO. 7 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Draft AD Form 944A: Documentation of Release of Exotic Microorganisms for Biological Control

SEE NO. 20 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

**Proposed ARS Guidelines for
the Importation, Interstate Movement, and Field Release in the United States
of Foreign Beneficial Organisms (Microbial Pathogens and Antagonists)
for Biological Control of Plant Nematodes and Plant Pathogens,
and for the Export of Such Organisms (Foreign and Native) for Research ¹**

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Attachments

1. Proposed Flow Chart for Introduction and Release of Foreign Biological Control Agents for Plant Pathogens and Nematodes
2. PPQ Form 526: Application and Permit to Move Live Plant Pests and Noxious Weeds
3. List of Plant Regulatory Officials of U.S. States and Territories
4. Proposed AD Form 944: Record of Shipment of Exotic Microorganisms for Biological Control
5. Proposed List of Biological Control Agents for Plant Pathogens and Nematodes Exempted from the Requirement of a Formal Environmental Assessment
6. Proposed Criteria for Exemption of Biological Control Agents for Plant Pathogens and Nematodes from the Requirement of a Formal Environmental Assessment for Field Release
7. Proposed Abbreviated Protocol Document for Providing Data for Environmental Assessments for Initial Field Release of Biological Control Agents of Plant Pathogens and Nematodes: Short Format
8. Proposed Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Field Release of Biological Control Agents of Biological Control Agents: Long Format

Attachments (Continued)

9. **Proposed Criteria for Biological Control Agents Requiring Only an Abbreviated Protocol Document for Providing Data for Environmental Assessment Information (Short Format)**
10. **List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries**
11. **Proposed AD Form 944A: Documentation of Release of Exotic Microorganisms for Biological Control**
12. **Proposed Repositories for Cultures of Microbial Biological Control Agents for Plant Pathogens and Nematodes in the United States**

¹ Original draft prepared by J. R. Coulson; revisions by G. C. Papavizas and J. R. Coulson, with comments provided by D. R. Fravel, R. N. Huettel, A. Y. Rossman, and N. G. Vakili (ARS), and C. J. Gabriel (CSRS), following review by Working Session participants (see Appendix 1) in January, 1991.

I. Intent and Scope of these Guidelines.

The field of biological control of plant pathogens and nematodes with the use of microbial pest control agents (MPCAs, antagonists) is relatively new compared to classical control of insects. It is only since the 1970s that plant pathologists and nematologists have begun in earnest research on the use of MPCAs (hyperparasites, antibiotic-producing microorganisms, competitors for food and space, hypovirulent strains) for augmentation-type control by applying such organisms to seeds, bulbs, tubers, soils, containers, soilless mixes, and sprays on plants, to control plant nematodes and pathogens. There has been even less research on the use of arthropod, nematode, and other invertebrate natural enemies of plant nematodes. And very little of the research on biological control of plant pathogens and nematodes has involved the *importation* of foreign organisms, but such research, especially involving the MPCAs, can be expected to increase.

There are several principles and concepts to keep in mind regarding the importation, containment, and release of foreign MPCAs.

- 1) Potential MPCAs, especially those for control of soilborne plant pathogens and nematodes, are immobile with very little chance for movement from the site of application. Therefore, they are easy to contain.
- 2) Exotic potential MPCAs are almost exclusively imported as pure cultures. Even when small amounts of soil are imported, microorganisms are isolated and maintained as pure cultures and the soils are autoclaved.
- 3) In plant pathology and nematology, potential MPCAs are not imported for relatively immediate use in the field. Instead, they are imported for laboratory and growth chamber studies after which one or two strains are selected for later field study.
- 4) Every soil, cultivated or virgin, the forest litter, decomposing organic matter, the plant rhizosphere and spermosphere, from any part of the United States, can provide potential MPCAs enough for studies lasting many years. Therefore, there is no urgent need for extensive study of exotic MPCAs.
- 5) Quarantine needs and procedures should be based on the nature of the exotic organism, not on its intended use. That is, regulatory considerations regarding exotic microorganisms intended for study for biological control should be no different from considerations given the importation of other exotic microorganisms for other purposes, e.g., N-fixation, phosphate solubilization, straw decomposition, etc.

The Guidelines presented here are intended to provide detailed procedures required for the importation and interstate shipment of foreign natural enemies and antagonists of plant nematodes and plant pathogens for diagnosis and laboratory research, and for biological control research and development programs that may involve field release of the foreign organisms in the United States. These procedures are designed to insure that every reasonable precaution will be taken to contain and prevent the escape or release of organisms that are injurious to agricultural, horticultural or forestry commodities, humans and domestic animals, or other beneficial organisms, or that are otherwise detrimental to the environment.

Organisms for which these Guidelines are intended include all foreign species, or strains, of fungi, bacteria, protozoa, viruses, rickettsias, and mycoplasmas (including spiroplasmas), and other microorganisms (MPCAs) that are imported for study or utilization as natural enemies or antagonists in the biological suppression of nematode pests of plants and microbial plant pathogens, and for imported host materials infected with these organisms. These Guidelines do not concern importation or other use of commercial products of such organisms, for which other guidelines may apply.

Draft Guidelines (F, page 4)

Separate ARS Guidelines exist for the importation and release of arthropod-parasitic nematodes, plant pathogens for control of weeds, microbial pathogens of arthropods, and invertebrates for biological control of arthropods and weeds. Though there is little probability that foreign arthropod, nematode, or other invertebrate natural enemies of nematodes will be imported for biological control of plant nematodes, if such research is intended, importations of such organisms should follow the Guidelines for other types of invertebrate biological control agents, the Guidelines most useful being those for arthropod-parasitic nematodes.

[FOLLOWING PARAGRAPH NEEDS REVIEW BY SCIENTIFIC PANEL.] **These Guidelines also include procedures for the export of foreign or domestic organisms to other countries for research on biological control of plant pathogens and nematodes.**

Field testing, development, and utilization of microbial pathogens and antagonists of domestic origin in the United States, research leading to the development of potential microbial pesticide products utilizing either foreign or native organisms, and research on genetic engineering of organisms, will be guided by separate authority and guidelines.

Some organizational abbreviations used in these Guidelines are:

APHIS - Animal and Plant Health Inspection Service, USDA

ARS - Agricultural Research Service, USDA

BCAC - Interagency Biological Control Advisory Committee **Proposed**

BCDC - Biological Control Documentation Center, ARS

BPDL - Biocontrol of Plant Diseases Laboratory, ARS

EPA - Environmental Protection Agency

FWS - Fish and Wildlife Service, USDI

NL - Nematology Laboratory, ARS

NPS - National Program Staff, ARS

PPQ - Plant Protection and Quarantine, APHIS

SBML - Systematic Botany and Mycology Laboratory, ARS

USDA - United States Department of Agriculture

USDI - United States Department of the Interior

II. Summary of Procedural Policies and General Safety Considerations.

A. Summary of Procedures for Importation, Interstate Shipment, Field Release, and Export of Biological Control Agents for Plant Nematodes and Plant Pathogens.

The Plant Quarantine Act of 1912 and the Federal Plant Pest Act of 1957 prohibit the importation and movement of pathogens, vectors, and articles that might harbor these organisms, unless authorized by the U.S. Department of Agriculture (USDA). The National Environmental Policy Act of 1969 (NEPA) contains provisions that impact upon the release of exotic organisms into the environment. Regulations under these Acts are enforced by the Plant Protection and Quarantine Programs (PPQ) of the Animal and Plant Health Inspection Service of the USDA.

The Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (FIFRA), as amended, authorizes the Environmental Protection Agency (EPA) to provide regulations concerning the development, movement, and use of pesticides, which by definition includes the development and utilization of microbial pesticide products. ARS scientists are required to have knowledge of and adhere to those EPA regulations

in development of pesticide products involving microbial organisms of both foreign and domestic origin. EPA guidelines for microbial pesticides appear in 40 CFR Part 158 Subpart M, Part A "Microbial Pest Control Agents." Note: Those guidelines do not cover importation or other movement of agents.

The determination of the adequacy of quarantine or containment facilities for receipt and laboratory testing of foreign organisms, and of the technical competence of investigators, is the responsibility of APHIS and pertinent State Departments of Agriculture. Determining the requirements that must be met for introduction of such organisms into containment and into the field is also their responsibility. [NOTE: THE FOLLOWING STATEMENT CONTAINS A PROPOSAL AND IS RETAINED PENDING ACTION BY ARS, APHIS, AND OTHER AGENCIES.] Also, for certain kinds of foreign organisms for biological control, an interagency Biological Control Advisory Committee (BCAC) has been (proposed to be) established to provide technical support and advice to APHIS and researchers, upon request, on certain proposed importations and releases in the United States. The BCAC generally may likely have little use in the case of biological control agents of plant pathogens and nematodes. [CLOSE OF STATEMENT] APHIS and BCAC are concerned that safety considerations such as those listed below are made prior to importation or field release of foreign biological control organisms in the United States.

At this point, it must be stressed that quarantine/containment needs and procedures for foreign MPCAs intended for research on biological control of plant pathogens and plant nematodes can be less stringent than those for other types of foreign biological control organisms for the reasons listed in Section I of these Guidelines.

Certain of the below listed safety considerations can be made before importation of the proposed biological control agent, while others can be made during the domestic containment or research phases of the introduction program. The procedures detailed in these Guidelines are designed to assure that such considerations are made and necessary precautions are taken.

The following references are recommended reading in conjunction with these Guidelines: Baker and Cook (1974); Cook and Baker (1983); Lima (1983); Coulson and Soper (1989); and Howarth (1991).

The more important conditions required for the importation and release of foreign organisms for control of nematode and microbial pests of plants, as reflected in these Guidelines, are illustrated in Attachment 1, and can be summarized as follows:

- 1) All foreign organisms shipped to the United States or later shipped interstate must be shipped in containers meeting USDA standards, and must be shipped with APHIS approval. See Sections III.B and V.B.
- 2) "Excluded" microorganisms, i.e., pure cultures of identified microorganisms that are known to be nonpathogenic for or parasitic on plants (plant pests) or animals, may be imported, with proper documentation, under provisions resulting in issuance of a "courtesy permit label." See Section III.A.
- 3) All foreign non-excluded organisms for biological control, except as noted in item 4, must be received, under APHIS permit and with proper documentation, in facilities approved by APHIS, where at least preliminary examination under containment will be made and all contaminants and other materials deemed to be of potential hazard or detriment are to be destroyed, and where the foreign material will be stored and/or all or portions re-routed to other competent and approved laboratories, as may be deemed necessary or desirable. See Sections III and IV.

4) Identified candidate non-excluded microbial biological control agents that can be shipped in pure culture in a test tube may be imported, with proper documentation, into various non-containment facilities approved by APHIS, under provisions resulting in issuance of "courtesy permit labels." See Section III.A.

5) Importation of organisms in host plant material or soil is permitted only when necessary (e.g., for isolation of microbes for diagnostic purposes), and such importations shall be made through an appropriate approved quarantine/containment facility under special APHIS permits. See Sections III and IV.

4) Identification of the foreign organisms are required prior to their consignment from containment, or prior to importation, in the cases noted in items 2 and 4 above. See Sections II.A, III.A, IV.B, and V.A.

5) Necessary testing must be conducted prior to consignment from containment. See Sections II.B, IV.B, and V.A.

6) Evaluation of the potential impact of the proposed release on nontarget organisms, and other safety considerations as listed below must be made prior to field release of the organism. An Environmental Assessment may be required prior to initial field release of the organism in the United States. See Sections II.B, IV.B, and V.A.

7) Determination of "native" biological control agents of the target pest or close relatives present in the proposed field release site is highly recommended. See Section V.C.

8) Voucher specimens to document the field release of exotic organisms are required, and certain other documentary procedures are to be followed, during which provisions should be made to keep APHIS and other officials informed of shipments and all releases. See Sections III.C, IV.C, and V.D and E.

9) For export of microbial and other organisms for research purposes, adherence to quarantine requirements of the pertinent foreign countries is necessary prior to the shipment of the organisms into those countries. See Section VI.

B. Safety Considerations Required for Importation and Field Release of Foreign Biological Control Agents for Plant Nematodes and Plant Pathogens in the United States.

The following safety considerations, discussed further throughout these Guidelines, must be evaluated prior to considering the importation or release of foreign organisms for biological control of nematode and microbial pests of plants into the United States:

1. Protection Against Entry of Plant Pathogens or Weeds.

a. Entry of host plant material or soil must be restricted as much as possible; if entry of foreign plant material is required (e.g., for diagnostic purposes or isolations), it must be initially received in approved quarantine/containment facilities, under special APHIS permit.

[THE FOLLOWING PARAGRAPHS HAVE BEEN RETAINED PENDING CONSIDERATION BY SCIENTIFIC PANEL.]

b. Provisions are required for the elimination of all contaminants or secondary organisms, and for screening candidate microbial biological control agents for plant pathogenicity and hyperparasites.

2. Protection Against Entry of Organisms Hazardous or Nuisances to Humans or Domestic Animals.

a. Knowledge is required that the foreign candidate biological control agent will not induce infection on vertebrates, or that the organism does not produce severe allergic reaction in humans, i.e., does not have potential as a major common allergen, prior to field releases.

[END OF RETAINED PARAGRAPHS]

3. Protection Against Entry of Organisms Inimical to Native or Other Introduced Non-Target Organisms.

a. The potential effect of the biological control agent on non-target organisms, e.g., native plants or invertebrates of economic or ecologic value, endangered and threatened plant or invertebrate species, etc., must be considered.

The degree of risk involving potential detrimental effects of a biological control agent on non-target organisms (as in 2 and 3 above) should be weighed against the potential beneficial effects of the agent. Whenever possible, information needed in these cases should be obtained from field studies in the country of origin, rather than entirely from laboratory tests.

III. Initial Importation of Foreign Organisms for Biological Control of Plant Pathogens and Nematodes.

Research workers should obtain as much pertinent information as practical concerning foreign biological control agents proposed for importation prior to their shipment to the United States. This information should include, if possible, an identification of the organism and pertinent biological information based on literature reviews and foreign field and laboratory studies, to assess the potential usefulness and safety of the candidate biological control agent.

Precautions as indicated in this Section of these Guidelines are designed to provide for the safe shipment and receipt of all foreign microbial biological control agents for nematode and microbial pests of plants, regardless of the amount of preliminary information obtained.

All potential biological control agents for nematode and plant pathogen pests shipped to the United States from foreign sources must: 1) have either APHIS shipment permit labels or "courtesy" labels affixed to the outside of the packages; 2) generally be shipped in containers meeting certain specifications; 3) be accompanied by specified documentation; and 4) be routed to and received and opened in designated APHIS-approved facilities, with certain exceptions.

Inclusion of plant or host material, or soil, in shipments from foreign sources will be limited to those cases in which such inclusion is a necessity. Should potentially useful organisms and/or host material not covered by APHIS permits or authority be received in quarantine, APHIS should be notified immediately and positive identification made for post-shipment approval.

A. Approvals, Permits, and Shipment Labels for Importation.

1. General Procedures.

APHIS permits for importation of "excluded" organisms, i.e., identified organisms known to be nonpathogenic to plants or animals, are not required. However, ARS policy requires the use of APHIS-issued "courtesy" shipment labels for foreign shipments of such organisms to the United States.

APHIS permits and shipment permit labels are required for importation of pure cultures of non-excluded beneficial organisms and of diseased host material or soil from foreign sources for diagnostic purposes or laboratory research. Special individually issued permits and permit labels will be required for the importation and later interstate movement for each individual shipment or series of shipments from foreign sources containing a) live diseased nematode hosts; b) infected plant material; and c) soil. However, individual shipments or series of shipments of candidate microbial biological control agents that can be shipped in pure culture in a test tube or similar container may be imported through use of APHIS-issued "courtesy" shipment labels.

An APHIS permit and shipment permit labels or "courtesy" shipment labels for individual shipments or series of shipments of biological control agents for plant nematodes and plant pathogens from foreign areas shall be requested by the intended recipient by completion of Section A of PPQ Form 526, Application to Move Live Plant Pests and Noxious Weeds (Attachment 2). [STATEMENT ADDED FOR CONSIDERATION BY SCIENTIFIC PANEL.] (Note: Proposed PPQ/ARS Form __, Application and Permit to Move Living Beneficial Organisms, is proposed to be available for use in obtaining permits, shipment permit labels, or "courtesy" shipment labels, for non plant or animal pests, or "potential pests;" see Guidelines for other type of biological control agents.) [END OF STATEMENT] Particularly important information to be included on this form are whether the organism to be imported is an "excluded" organism or not, indications of any host material (plant or nematode) or soil to be included in the shipments, if any, the APHIS-approved facility to which the shipments are to be initially sent, and the intended final destination of the biological control agent material. Arrangements must be made with the designated ARS receiving facility for receipt, handling, and any transshipment well in advance of intended importations. The application (PPQ Form 526) should be sent to the regulatory official of the State in which the final destination is located, with a request that Section B of the form be completed and that the form be forwarded to APHIS-PPQ. See Attachment 3 for a list of the addresses and telephone numbers of State regulatory officials.

To expedite importation of excluded organisms or pure cultures of biological control agents of plant pathogens and nematodes, APHIS-PPQ, upon receipt of a request on PPQ Form 526, will issue courtesy type permit labels without a formal permit prescribing safeguards for the movement. Pure cultures of beneficials do not require permits when they are an "excluded" organism or otherwise determined by APHIS not to be plant or animal pests. Pure cultures of biological control agents on which APHIS has issued courtesy permits will be received directly by the applicant for experimentation (see flow chart, Attachment 1).

Before PPQ acts on permit applications for other non-excluded materials, often including host material or soils, they will consult with pertinent microbiologists or other scientists of the receiving facilities or other organizations, and State (see Attachment 3) and other regulatory officials as warranted. After these consultations, PPQ will either issue a permit for the importation(s), deny the request, or request additional information prior to making a decision. The permit consists of the completed PPQ Form 526 indicating PPQ approval and any special stipulations in Section C of the form. If importation is approved, PPQ will send the permit to the applicant, with copies to the appropriate receiving facilities and State regulatory officials and to the BCDC. PPQ will also send appropriate shipment permit labels to the applicant for forwarding to the shipper. A shipment label will be placed on the outside of each shipment package, to facilitate passage of the shipment through the mails or customs. The shipment permit labels indicate PPQ authorization of the shipment.

These permits and shipment permit or "courtesy" labels are generally valid only for initial receipt of shipments of foreign material. See Sections V.B and C of these Guidelines for procedures for interstate shipments and for field release of imported organisms. Supplies of the PPQ Form 526 permit application are available from APHIS-PPQ or ARS-BCDC.

2. Special Procedures for Importation: Specially-Designated Domestic Receiving Facilities.

APHIS can issue permits and shipment permit or "courtesy" labels on a blanket basis to ARS and other domestic locations approved for initial receipt of shipments of foreign biological control agents for plant pathogens and nematodes from overseas locations. Issuance of these permits and supplies of shipment labels will be for shipments of pure cultures of biological control agents, or in some cases for shipments including dead plant or animal material or soil harboring biological control organisms, and will be made in response to a PPQ Form 526 application accompanied by a memorandum explaining in appropriate detail the purposes for which the permits and labels are intended. PPQ Form 526 application forms, with Section A completed by the applicant, and explanatory memoranda will be sent to the appropriate State regulatory official (see Attachment 3) for State approval. Approved forms and memoranda will be forwarded to APHIS-PPQ by the State officials.

PPQ will provide the BCDC and the appropriate State regulatory officials with a record of shipment labels issued, and the recipients of the labels will furnish PPQ, BCDC, and State regulatory offices with a record of foreign material imported under these special procedures on a periodic basis (see also Section IV.C of these Guidelines).

3. Shipments to Non-Quarantine Facilities.

The requirement for initial receipt in specially approved ARS facilities may be waived in cases of some shipments entering the United States from Canada and Mexico, and in certain other cases as determined by PPQ. However, a courtesy permit label for such importations is still required, which may include consultation with appropriate research and regulatory personnel.

B. Shipping Containers for Importation.

Shipping containers will vary according to the requirements of the material to be shipped. However, in all cases, material from foreign sources must be shipped in a container within a container, both of sturdy construction and capable of being sealed. The outer container should be of sturdy impact-resistant material and be enclosed in finely-woven, securely sealed, heavy cloth or canvas, or heavy wrapping paper. The inner container may be of metal, wood, heavy glass, cardboard, or plastic, and should be securely sealed; this container may also be wrapped and sealed in paper, tightly-woven cloth, or other type sealing materials. Approved packing materials necessary for cushioning the inner package within the larger container, include absorbent cotton or processed cotton free of cottonseed, cellulose or plastic materials, excelsior, paper or paper products, sponge rubber, or vermiculite.

Both the inner and outer container and all packing material will be destroyed or otherwise treated by incineration, heat or other methods, after contents are removed in the receiving facility, in such a manner that any included pathogens or other organisms are destroyed. Specific procedures will be indicated in the facility's Operational Procedures (see Section IV.B).

[THE FOLLOWING SECTION IS RETAINED FOR CONSIDERATION BY SCIENTIFIC PANEL]

C. Documentation of Importation.

All shipments or series of shipments of a microbial biological control organism from foreign or overseas sources shall be accompanied, or otherwise documented, by an AD Form 944 (Attachment 4), with Section I of the form completed in accordance with instructions on the form. Completion of this form provides source, culture, and other information for the recipient of the shipment, and feedback information for the shipper on the results of the shipment. All ARS and other overseas laboratories and personnel engaged in shipping biological control agents to the United States, and all approved domestic ARS receiving facilities for exotic biological control organisms, will be provided by the BCDC with a supply of these forms, and the forms will be issued by them or by BCDC to explorers or other overseas shippers when notified by PPQ of the issuance of an importation permit or shipment labels. In cases where a shipment or series of shipments of a biological control organism is received without AD-944 type documentation, the receiving facility will be responsible for completion of Section I of the AD Form 944 with information to be obtained from the shipper or other sources. See also Section IV.C for further documentation activity upon shipment receipt.

Though such shipments are unlikely, should shipments of invertebrate natural enemies of nematodes from foreign or overseas sources ever be made, such shipments should be documented using AD Form 941, Biological Shipment Record - Foreign/Overseas Source. Examples of this form are included in Guidelines for importing foreign invertebrate biological control agents, and supplies are available from the BCDC.

[END OF RETAINED SECTION]

IV. Facilities, Personnel, and Operational Procedures for Receipt of Foreign Biological Control Organisms for Plant Pathogens and Nematodes.

All ARS facilities charged with responsibility for the initial receipt and clearance in the United States of foreign biological control agents for plant pathogens and nematodes must conform to certain required physical qualifications, and must operate under special permit conditions as may be required by APHIS and pertinent State quarantine regulatory agencies. These permit conditions, which will be monitored by APHIS, will stipulate certain operational and documentation procedures required for operation of the facility in the receipt, handling, and transshipment of foreign biological control agents.

A. Type of Facilities Required for Initial Receipt of Foreign Biological Control Agents for Plant Pathogens and Nematodes.

There are no special facility requirement for receipt of foreign shipments of pure cultures of "excluded" organisms, other than standard microbiological laboratory facilities. However, ARS facilities to be engaged in initial receipt and transshipment of foreign non-excluded biological control agents of plant pathogens and nematodes, or of these agents for which APHIS has not issued a formal permit, are required to have containment/quarantine laboratories. These laboratories are to be inspected and approved for importation of foreign material by authorized representatives of PPQ prior to issuance of an importation permit authorizing such operations. The inspection will be conducted to insure that adequate physical safeguards exist to minimize or eliminate the possibility of escape of organisms from the containment/quarantine laboratory within the facility.

These physical safeguards of a Quarantine/Containment Laboratory (QL) for Biological Control Agents of Plant Pathogens and Nematodes, which may vary depending upon the type of organisms to be received, shall include:

1. Anteroom entryway with air pressure positive to isolation area.
2. Floors, walls, ceilings, windows and doors able to withstand decontamination operations.
3. Sealed, or otherwise pathogen-, insect-, mite-proof electrical system, including floor plugs, switches and lights.
4. Capability for isolating fungi, bacteria, viruses, and nematodes within the QL (e.g., four separate transfer compartments within the lab equipped with microbiological hoods, UV lights, negative air pressure).
5. An autoclave for decontaminating laboratory wastes and extraneous foreign material.
6. Heating and exhaust system, preferably, a closed-air system, fitted with adequate filters.
7. Plumbing system designed to prevent escape of nematodes and pathogens, including screening floor drains and other accessible drain lines and passage of soil or sewage through a decontamination system.
8. Access of heat system to containment area; preferably the system should be available through a sealed exit direct from containment room.
9. Access to facility limited to workers directly assigned to quarantine program or under the direct supervision of those engaged in quarantine/containment operations.
10. Pressurized air system-positive pressure in non-containment areas, negative pressure in containment areas.

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11. Provision for shower room and change of clothes; optional.

If physical safeguards are deemed to be adequate after inspection by PPQ, or following the rectification of any deficiencies found during inspection, and subsequent issuance of an importation permit (see Section III above), APHIS-PPQ will issue a dated and renewable certificate indicating approval for operation of the facility as a primary receiving center for foreign biological control agents for plant pathogens and nematodes. This certificate should be prominently displayed by the approved facility. APHIS officials will conduct unannounced re-inspections of the facility to assure the continuing adequacy of these physical safeguards. State regulatory officials are also authorized to inspect the facilities upon their request.

The ARS facilities having such approved Quarantine/Containment laboratories will provide address labels and pertinent shipping instructions, including instructions to airline, post office, and customs officials as appropriate, to ARS and other overseas laboratories and personnel upon request, or to the permittee (applicant) upon notification of issuance of a permit for shipment to be received at those facilities (see Section III.A.1).

B. Facility Personnel and Operational Procedures.

1. Receiving Facility Personnel.

Each major ARS facility approved for receipt of foreign biological control agents for plant pathogens and/or nematodes will have a designated Quarantine (or Containment) Officer (QO), or other designated person responsible for documenting importations, transshipments, and releases of such organisms. These will be appointed by the appropriate ARS official after consultation with the NPS, Research Leaders or Laboratory Chiefs, and Area or Center Directors. The QO will be thoroughly trained in quarantine philosophy and containment operational procedures for the organisms to be contained. The QO of a Quarantine Laboratory (QL) must have an advanced degree in microbiology, will report to the Research Leader or Director of the facility, and will be responsible for assuring that the QL's operational procedures are followed. Specific responsibilities include:

- a. The QO will have exclusive control over quarantine actions (including importation and consignments from quarantine) which are authorized by APHIS;
- b. Maintenance of the physical safeguards of the QL as listed in Section IV.A.
- c. Adherence to permit, documentation, voucher, and other specifically required procedures or restrictions on types of materials to be received or shipped, as may be required by APHIS and the regulatory agencies of the State in which the facility is located;
- d. Proper confinement of all organisms in the containment laboratory, as may be required, and handling of these organisms, alone or by any other worker assigned to the quarantine program, in a manner to prevent escape of organisms;
- e. With the assistance of the facility's scientific personnel, obtaining authoritative identification of the organisms to the extent as may be required, if not already obtained;
- f. Authorizing the consignment of organisms from quarantine after any necessary screening and authorization by APHIS; and
- g. Packaging and transshipment of organisms in such a manner as to prevent their escape during transport.

Ultimate responsibility for the consignment of organisms from the QL or their shipment from the facility rests with the Research Leader of the facility, who in certain cases may himself be designated Quarantine (or Containment) Officer.

Other personnel assigned to the containment program will be limited in number, and thoroughly instructed in the operational procedures. A list of personnel authorized access to the QL will be prepared and prominently posted. All other personnel will be denied access to the this area unless accompanied by the Quarantine Officer or his designated representative.

2. Operational Procedures.

Each ARS facility having an approved Quarantine (or Containment) Laboratory (QL) will prepare specialized operational procedures (see flow chart, Attachment 1), which may differ depending on the location, primary mission, physical construction, staffing of the facility, and the type organisms involved (different procedures may be needed for fungi, viruses, or nematodes, and for soils or plant materials, etc.). These operational procedures will be approved by appropriate ARS line and staff officials, and by APHIS and State regulatory officials prior to issuance of an importation authorization permit and certificate authorizing operation of the facility for receipt of foreign biological control agents for plant pathogens and/or plant nematodes, whichever may be the case. The approved Operational Procedures will be posted near the entrance of the quarantine/containment area of the facility. APHIS officials will conduct periodic unannounced inspections of the facility to ascertain that these procedures are being followed, and State regulatory officials may also conduct such inspections.

Operational procedures must include:

- a. Permit and approval procedures for importations (see Section III.A), including provision for handling unsolicited shipments arriving without proper permits or approvals, and for following other specific procedures as may be stipulated in the importation permit.
- b. Provisions for assuring maintenance of quarantine/containment conditions, including limited access to containment areas, and requirements for protective clothing, etc.
- c. Provision for opening of incoming shipments only in special containment areas within the main quarantine area.
- d. Description of means of destruction or sterilization of shipping containers and packing material within quarantine.
- e. Means for quarantine screening of imported material and for elimination of inadvertently, inappropriately, or necessarily included organisms such as plant material, nematode hosts/prey, or contaminants. In all cases, only healthy domestic host/prey material will be used if required to maintain cultures of the organisms in quarantine.
- f. If cultures may be contaminated with other organisms, purification of such cultures by means approved in microbiology, plant pathology, virology, or nematology.
- g. Means for obtaining rapid authoritative identification of organisms received in quarantine, to the extent as may be required.
- h. Detailed protocol to be followed prior to consignment of organisms from maximum quarantine containment area for further testing as required, or prior to the decision to release organisms from quarantine for further shipment or field release. This protocol should include consideration of the known or tested host range and relationships of the species or of the taxonomic group to which it belongs, its potential effect on other beneficial organisms, adequacy of safeguards for elimination of

contaminants, adequacy of taxonomic identifications, and other safety considerations listed in Section II.B of these Guidelines. See also Section V of these Guidelines.

- i. Means for quarantine storage of the imported organisms as may be required.
- j. Shipping procedures, including proper packaging (see Section V.C of these Guidelines).
- k. Documentation procedures (see Sections III.C, IV.C, and V.E of these Guidelines).
- l. Voucher procedures (see Section V.F of these Guidelines).
- m. Provisions for monitoring of the Operational Procedures by the Research

Leader or Laboratory Chief of the facility.

[THE FOLLOWING SECTION IS RETAINED FOR CONSIDERATION BY SCIENTIFIC PANEL.]

C. Documentation of Receipt of Imported Material.

The Quarantine Officer or other designated person of each ARS facility approved for receipt of foreign microbial material is responsible for completion of Section II of either the AD Form 944 (Attachment 4), which should accompany each shipment of foreign material received (see Section III.C of these Guidelines), and for filing and distribution of the copies of these forms according to instructions on the form. The Quarantine Officer is also responsible for assuring that these forms are included in all incoming shipments, or for their preparation if not so included.

Though such shipments are unlikely, should shipments of invertebrate natural enemies of nematodes from foreign or overseas sources ever be made, such shipments should be documented using AD Form 941, Biological Shipment Record - Foreign/Overseas Source. Examples of this form are included in Guidelines for importing foreign invertebrate biological control agents, and supplies are available from the BCDC.

A record of all foreign shipments and species received in the receiving facility will be maintained, and provided, upon request, to BCDC, PPQ, and the pertinent State regulatory agency, as may be stipulated in the importation permit. See also Section V.D for additional records to be provided by the receiving facility.

The Quarantine Officer should retain properly preserved specimens of incoming material, and of original host/prey material, if available, to serve as vouchers representing material received in quarantine. See Section V.E for additional information concerning voucher specimens.

[END OF RETAINED SECTION]

V. Quarantine Consignment, Interstate Shipment, and Field Release of Foreign Biological Control Agents for Plant Pathogens and Nematodes.

The ultimate responsibility for the release/consignment of an organism from quarantine rests with the Research Leader or Laboratory Chief of the ARS receiving facility, although authority for making this decision may be delegated to a designated Quarantine Officer under certain circumstances. Procedures and considerations required prior to release from containment are included in the Operational Procedures approved by APHIS (see Sections IV.B.2.h and V.A of these Guidelines). The Quarantine Officer is

responsible for: a) Assurance that safety considerations (see Section II.B) are made prior to release of the organism from quarantine conditions, or that proper arrangements are made for any additional testing deemed to be required; b) Documentation procedures involved following release from quarantine; c) Preparation of voucher specimens as appropriate; d) Assurance that any necessary authorizations for interstate shipment and/or field release of the organism are obtained (see Sections V.B-C below; and e) Preparation of specific detailed protocols to be followed prior to consignment of the organism from quarantine/containment (such protocols should include review, clearance, and any testing procedures required prior to consignment of foreign organisms from quarantine). In general, no such detailed protocols are required for excluded organisms, i.e., non plant or animal pests, though specific information will be required prior to the initial field release of these organisms in the United States.

A. Quarantine Review and Clearance Procedures.

The first step in quarantine clearance procedures must be to obtain an authoritative morphological and/or biological identification of the organism. No live material with insufficiently known host relationships will be permitted to leave quarantine. As may be needed, tests should be made to assure that all contaminants have been removed from the material to be consigned from quarantine.

In cases where insufficient knowledge of the foreign non-excluded organism is available, certain other tests may be required, which may or may not need to be conducted under quarantine conditions, as may be determined by the QO with APHIS approval. For example, certain protozoa, fungi, viruses, and other microbial organisms may require testing for pathogenicity to plants or animals, and bacteria and other pathogens requiring propagation in susceptible nematodes might need to be propagated under quarantine conditions (and if so, the nematodes must be of domestic origin, unless special APHIS permits have been received, and should be securely contained in quarantine). Some foreign pathogens may need testing on selected beneficial invertebrates or plants, to include endangered species as may be warranted, prior to field release in the United States (see safety considerations listed in Section II.B of these Guidelines).

The Quarantine Officer, with the pertinent researcher involved with the non-excluded organism (i.e., actual or potential plant or animal pathogens), and with the approval of APHIS, will determine clearance for consignment of the organism from quarantine by means of a critical review of available ecological and biological information based on the taxonomic identification of the organism and discussions with relevant knowledgeable experts, including other microbiologists, taxonomists, and biological control research workers. During this review, special attention will be made to the safety considerations listed in Section II.B of these Guidelines. Based on this review of information and discussions, conclusions are reached by the Quarantine Officer by which the identified organism is assigned to one of three quarantine clearance categories:

Class A: The organism is considered dangerous or otherwise unsuited for continued experimentation. All material placed in this category must be destroyed in quarantine.

Class C: The organism is considered a promising biological control agent, but specific additional studies are deemed necessary before field release can be permitted. Material placed in this category may be given clearance for consignment to other researchers within the receiving facility

or for interstate or other shipment to appropriate researchers at other facilities of such design as to prevent escape during conduct of the needed studies. See Section V.B for further procedures.

Class D: The organism is considered safe for field release in the U.S., based on previous release clearances. Organisms placed in this category may be consigned to non-quarantine personnel of the receiving facility for field release or shipped interstate following procedures stipulated under Sections V.B-C.

B. Interstate Shipment from ARS Facilities Engaged in Receipt, Propagation, or Storage of Foreign Biological Control Agents for Plant Pathogens and Nematodes.

The intended recipient of foreign biological control agents for nematode pests or plant pathogens to be shipped through or otherwise received from ARS facilities, shall be responsible for ascertaining whether any State approvals for such shipments exist in the State in which the organism is to be received, and for obtaining those permits as required. In general, there is no requirement for APHIS permits for interstate movement of foreign excluded microbial organisms or for non-excluded microbial organisms assigned to Classes C and D (see Section V.A above). However, if the material is to be field released by the recipient, this intent must be clearly indicated, in which case the Quarantine Officer or other responsible person of the ARS shipping/receiving facility must ascertain whether the necessary approvals for such release, as noted in Section V.C below, have been obtained before shipment of the organisms can be made.

If a State permit for the shipment is required, the PPQ Form 526 or the proposed **PPQ/ARS Form __ ?**; see Section III.A can be used to obtain the permit, and a copy of the permit will be forwarded by the proposed shipment recipient to the ARS facility making the shipment, after which the shipment(s) may be made. The Quarantine Officer or pertinent non-quarantine personnel will maintain a file of such State approvals, and will provide copies to APHIS and BCDC, upon request.

Arrangements for State approvals and/or APHIS permits for field releases must be made well in advance of intended shipments, to prevent the loss of valuable live materials while awaiting approval procedures.

All foreign biological control agents shipped from ARS facilities will: 1) be packaged in containers designed to prevent breakage or escape of the organisms during transport (see Section III.B); 2) have a PPQ courtesy shipping label affixed to the outside of the package, and 3) be accompanied by shipping record forms (see Section V.D).

ARS facilities may obtain a supply of courtesy shipping labels from APHIS or BCDC for use for shipments of pure cultures of microbial biological control agents under the permit issued for receipt of foreign shipments (see Section IV), for shipment to States not requiring a permit. These shipping labels will not be used for the rare cases in which live host materials (nematode pests) or plant material are to be included in the shipments; in these cases, specific APHIS-issued permits and permit labels are required. No interstate shipments will be made by ARS facilities except under the conditions stipulated in the facilities' importation permit received from APHIS.

ARS facilities involved in interstate shipment of foreign organisms will maintain a record of such shipments and will provide, upon request, such records to appropriate regulatory agencies in the State in which the facility is located and to regulatory agencies of the States to which shipments have been made.

APHIS and BCDC shall be similarly informed, upon request. The Quarantine Officer(s) shall be responsible for maintaining such records for ARS facilities having quarantine laboratories.

C. Field Release of Foreign Biological Control Agents for Plant Pathogens and Nematodes.

1. General Approval and Permit Requirements.

Specific approval procedures for field release of foreign biological control agents for plant pathogens or nematodes include: a) A requirement for State approval and an APHIS permit for the initial field release of an exotic species in the United States, which may require preparation of an Environmental Assessment (EA) and notification of the EPA; b) A requirement for an Experimental Use Permit (EUP) from the EPA for field testing involving 10 acres or more of any microbial pathogen, foreign or domestic, during development of a microbial pesticide product; c) A requirement for an APHIS permit and State approval for all subsequent field releases of the approved foreign organism in other States; and d) Proper documentation of all initial and subsequent field releases of foreign organisms, including periodic notification of APHIS, BCDC, and pertinent State agencies. The Research Leader and other involved ARS personnel at ARS facilities proposing to release foreign biological control agents for field testing or establishment are responsible for adherence to these procedures.

All applications for State approvals and APHIS permits for field release of foreign biological control organisms for plant pathogens and nematodes for field testing or establishment shall be initiated by use of PPQ Form 526 (Attachment 2).

2. Federal and State Regulations.

Provisions must be made to meet the requirements of certain Federal and State regulations impacting the introduction of exotic organisms for biological control of pests. The Federal regulations involved, in addition to the Plant Quarantine Act (PQA) and Federal Plant Pest Act (FPPA) already mentioned in these Guidelines as regulating the importation and movement of live organisms, include the following: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the National Environmental Policy Act (NEPA); and the Endangered Species Act (ESA). The ARS Research Leader, Quarantine Officer, and involved researchers, are responsible for adherence to the requirements of regulations under these Acts as noted below.

FIFRA: Under this Act, which is administered by the Environmental Protection Agency (EPA), all biological agents used for control of pests are classified as pesticides, and thus their movement and use is regulated by EPA. EPA has exempted from regulation under FIFRA invertebrate biological control organisms on the grounds that they are adequately regulated by the USDA, primarily by APHIS under the PQA and FPPA and associated regulations. However, EPA regulations under FIFRA must be followed in the development of microbial pesticide products. EPA guidelines for microbial pesticides appear in 40 CFR Part 158 Subpart M, Part A "Microbial Pest Control Agents." Note: Those guidelines do not cover importation or interstate movement of agents.

NEPA: Under this Act, all Federal or Federally-supported agencies must consider the environmental impact of major actions that may significantly affect the quality of the human environment in

the U.S. USDA agencies interpret this to mean that, with certain exceptions, a formal Environmental Assessment (EA) is required for the initial field release of exotic biological control agents in the U.S. That is, an environmental risk analysis must be applied in such actions by ARS (ARS, 1986), and for the issuance of Federal permits by APHIS for the initial field release of introduced plant pests or potential plant pests. [THE FOLLOWING SECTIONS ARE RETAINED PENDING DECISIONS AND ACTIONS BY ARS AND APHIS.] A proposed list has been prepared ARS and other scientists of beneficial microbial organisms that offer little or no risk of having significant adverse effects on the quality of the environment, and thus are exempt from this requirement (see Attachment 5). The proposed criteria for excluding these organisms from the EA requirement prior to issuance of an APHIS permit are listed on Attachment 6 [NOTE: LIST OF EXEMPTED ORGANISMS AND CRITERIA IN ATTACHMENTS 5 AND 6 NEED TO BE REFINED BY THE SCIENTIFIC PANEL]. The list of exempted organisms may be amended by application to the ARS and/or APHIS Administrators. APHIS may issue permits for the initial field release in the United States of the types of organisms represented on the list without preparation of a formal EA, but may require applicants to submit additional information in lieu of an EA to resolve questions about the proposed release of a biological control agent.

For initial release of organisms not exempted from a formal EA requirement, environmental assessment protocols have been prepared, the complexity of which vary with the level of risk involved. Attachments 7 and 8 present formats or protocols for providing information required for developing an EA required prior to issuance of a permit for initial release of non-exempted organisms in the United States. Attachment 9 provides proposed criteria to determine the appropriate protocol to use. [ATTACHMENT 9 REQUIRES PREPARATION BY SCIENTIFIC PANEL.] In cases where the level of risk is high, an Environmental Impact Statement (EIS) will be required. [END OF RETAINED SECTIONS]

ESA: This Act, administered by the Fish and Wildlife Service (FWS) of the USDI, concerns the impact of Federal actions on native endangered and threatened animals (including invertebrates) and plants in the U.S. The safety evaluations noted in Section II.B.3 are designed to meet these concerns. Comments on these concerns and results of any test results related to them should be noted on the permit application or EA protocol document.

Several States have laws and regulations regarding environmental policy and/or endangered species within their boundaries, similar to NEPA and ESA. In addition, certain States have regulations requiring permits or approval prior to shipment or release of organisms within their borders, or have otherwise formally requested notification prior to such importations or releases (see Attachment 10). Knowledge of and adherence to pertinent State regulations are responsibilities of the involved ARS Research Leader, Quarantine Officer, and other involved researchers prior to the initial and subsequent releases of biological control organisms in the U.S.

3. Initial Releases of Foreign Biological Control Agents of Plant Pathogens and Nematodes in the United States.

Prior to initial field release of new foreign biological control agents for plant pathogens and nematodes in the United States, appropriate State approval(s) and an APHIS permit must be obtained on PPQ form 526 (Attachment 2) by the ARS quarantine facility or other facility proposing to make the initial release. Section A of form will be completed by the facility indicating the intent to field release the

biological control agent in the State, and the form will be sent to the pertinent State regulatory agency (see Attachment 3), along with an Environmental Assessment protocol document if required (see NEPA requirements above). If an EA is deemed not to be required, it must be documented on the permit application that criteria for exclusion of the organism from the EA requirement have been met. State approval will be indicated in Section B of the form, and the form will be forwarded by the State official to APHIS for completion of Section C indicating approval or disapproval of the release.

[THE FOLLOWING SECTION IS RETAINED PENDING DECISIONS AND ACTION BY EITHER ARS OR APHIS OR BOTH.]

If an EA is required, there are then two possible scenarios:

(1) An appropriate EA protocol document (see NEPA requirements above and Attachments 7-9) will be prepared by the permit applicant and included with the appropriate permit application form (PPQ form 526) when submitted to the State regulatory official in which the initial field release is intended. State approval will be indicated in Section B of the form, and the form will be forwarded by the State official to APHIS, where the document will receive an in-house review in APHIS, and/or by BCAC as may be requested. After a favorable review, APHIS will prepare an EA and, if this results in a Finding of No Significant Impact (FONSI), APHIS-PPQ will complete Section C of the permit application form. PPQ will return the completed form (which constitutes the permit) to the applicant, with copies to the involved Quarantine Facility (if this differs from that of the applicant), and to the BCDC and the pertinent State regulatory agency. The permits, valid for 5 years, may be renewed for another 5-year period, after which no further permits for release of the permitted organism in that State shall be required. The Quarantine Officer shall be responsible for permit renewals.

(2) For the second option, the ARS researcher proposing the initial U.S. field release of an introduced biological control agent will submit the appropriate EA protocol documents (see Attachments 7-9) to the pertinent ARS office for review. A FONSI will subsequently be prepared by ARS which will be then be included with the permit application form when sent to APHIS via the appropriate State regulatory agency. APHIS-PPQ may then issue the permit and send copies as in option 1. ARS will also notify EPA of the intended release with copies of all appropriate environmental documents, in order to comply with the current requirement of EPA notification of field studies of microbial organisms.

[END OF RETAINED SECTIONS]

These procedures pertain only to experimental field releases in test plots of less than 10 acres (or less than one acre of water). If field tests are required in larger areas, an EUP must be obtained from the EPA.

Though not required, it is highly recommended that surveys of the "native" organisms affecting the target nematode or plant pathogen and their close relatives in the initial and subsequent release areas be conducted prior to release of the foreign organism.

[FOLLOWING PARAGRAPH RETAINED PENDING APHIS AND ARS DECISIONS.]

At any time during the procedures for obtaining permits for field release, a (proposed) Biological Control Advisory Committee (BCAC) is available to provide technical support and advice to APHIS and ARS upon requests from research, administrative, or regulatory personnel. Since the BCAC is not expected to play a role in regard to release of foreign organisms for control of plant pathogens and nematodes, it is not further discussed in these Guidelines. Information on the proposed BCAC is available in Guidelines for other types of imported biological control agents. **[END OF PARAGRAPH]**

4. Subsequent Releases of Foreign Biological Control Agents for Plant Pathogens and Nematodes.

Completion by the Quarantine Facility or other shipping/releasing facilities of Section A of the PPQ form 526 for State regulatory agencies is also required for subsequent releases of the same organism in additional States. As for initial release, the PPQ form 526 will be forwarded, if release is approved, by the State official to APHIS-PPQ. Based upon prior release approval and State recommendation, PPQ will complete Section C and distribute copies of the completed form (the permit) as above.

After permits are obtained for their initial releases, no other prior action, except permit renewal as noted above, is required for subsequent field release of foreign biological control agents in States for which permits have been obtained. However, records of releases shall be kept by ARS facilities and provided, upon request, to appropriate regulatory agencies in all States in which releases are made. APHIS and BCDC shall also be similarly informed, upon request.

[THE FOLLOWING SECTION IS REQUIRES CONSIDERATION BY A SCIENTIFIC PANEL.]

D. Documentation of Shipments and Field Releases of Foreign Biological Control Agents for Plant Pathogens and Nematodes.

A photocopy of the original AD Form 944 (Attachment 4) documenting initial importation of the foreign material should be included with all consignments and shipments of foreign microbial organisms made by ARS quarantine receiving facility, with notes on subsequent isolation or culture history of the imported organism. It is highly recommended that all other ARS researchers provide copies of the original AD Form 944 and similar notes for all subsequent shipments of the foreign microbial material. Should foreign invertebrate biological control agents for nematodes ever be imported, an AD Form 942 (see Guidelines for invertebrate biological control agents) should be prepared for release or shipment from quarantine laboratories.

As noted in Section V.B above, ARS facilities approved for importation of foreign microbial biological control agents should maintain a record of all shipments of these organisms and provide a written record, upon request, to appropriate regulatory agencies in the State in which the facility is located, to such agencies of all other States to which shipments have been made, and to APHIS and BCDC. The Quarantine Officer(s) shall be responsible for such records.

The field release of foreign microbial organisms cleared for such release in accordance with procedures outlined in Section V.A-C should be documented by use of the AD Form 944A (Attachment 11), following instructions on the form. A single AD 944A form may be used to record multiple releases, noting a range of release dates in Section II of the form. Completion of these forms provides source, culture, and other information to document the field release. Copies of the completed forms should be sent to the pertinent ARS receiving facility, to BCDC, and APHIS-PPQ. Should foreign invertebrate biological control agents for nematodes ever be released, an AD Form 942 (see Guidelines for invertebrate biological control agents) should be prepared.

All ARS facilities with approved quarantine laboratories, and BCDC, will be provided with supplies of AD Forms 944 and 944A and will provide, upon request, supplies of these forms to persons and facilities engaged in non-quarantine culture, shipment, and release activities.

The Quarantine Officer of each ARS facility with quarantine laboratories shall be responsible for assuring proper documentation of consignments, shipments, and/or releases of foreign microbial biological control agents, using AD Forms 944 and 944A, and for distribution of the copies of the forms, as per instructions on the forms.

[END OF RETAINED SECTION]

E. Voucher Specimens.

Retention of specimens representing imported and released material is required in some cases, and is highly recommended in all cases, in order that vouchers relating to the importation and release of exotic organisms in the United States will be available for immediate or future study by taxonomists and biological control researchers.

Of particular importance are voucher specimens to document:

- 1) The first field release in the United States of a foreign biological control agent by quarantine or other facilities; these voucher specimens should include specimens from each major geographical area (at least from each country) of origin of the released material;
- 2) Subsequent field releases of the same species from new major geographical areas;
- 3) Field releases from long-established laboratory or storage cultures; and
- 4) The first additional field release of a newly imported foreign species if such releases are resumed after a period of three or more years after initial field release.
- 5) Retention of voucher specimens of the original and laboratory nematode host/prey or plant pathogen are also highly recommended.

[GENERAL GUIDELINES ARE NEEDED REGARDING PROPER PREPARATION AND STORAGE OF VOUCHER MATERIAL AND POSSIBLE REQUIREMENTS FOR SHIPMENT OF MATERIALS FOR RETENTION AT DESIGNATED REPOSITORIES OF VOUCHERED NEMATODES (NL) AND OF THE VARIOUS TYPES OF MICROBIAL ORGANISMS (SBML AND BPDF?), PROPOSED TO BE LISTED IN ATTACHMENT 12].

[THE FOLLOWING SECTION REQUIRES CONSIDERATION BY A SCIENTIFIC PANEL.]

VI. Export of Biological Control Agents for Plant Pathogens and Nematodes to Other Countries for Research Purposes.

All ARS domestic and overseas facilities and personnel making shipments of biological control agents to foreign countries for research purposes will determine whether or not quarantine regulations exist in the country to which the shipment are to be made, including any requirement for quarantine entry permits, and are responsible for adherence to those regulations, if any.

All shipments to foreign countries shall be shipped in containers designed to prevent escape of organisms. Host materials (invertebrates or plant) will not be included in the shipments unless absolutely required, and unless specific approval for such inclusion is obtained from the foreign government.

[PARAGRAPH RETAINED PENDING DECISIONS BY ARS AND APHIS.] Although not legally required, it is highly recommended that an APHIS-PPQ courtesy shipping label (or equivalent ARS form to be developed) be affixed to the outside of the package near the address labels, together with the

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foreign permit label, if applicable. These shipping permit labels may be obtained from ARS-BCDC, who will issue the labels only after receipt of documentary evidence that all foreign quarantine regulations have been met or that there are no quarantine regulations (e.g., photocopies of permits or relevant correspondence).
[END OF RETAINED PARAGRAPH]

As a courtesy and for the information of the foreign recipient, an AD Form 944 shipment record form (Attachment 4) (or AD Form 941 for invertebrates), with Section I completed, should accompany each shipment, with a request that Section II of the form be completed, and the form returned to the sender. The sender is responsible for distribution of copies of the form in accordance with instructions on the form.

Although no voucher specimens are required, it is highly recommended that the sender of shipments to foreign countries retain such specimens to document the contents of the shipments for possible future reference.

[END OF RETAINED SECTION]

VII. Recommended References.

Agricultural Research Service. 1986. Final regulations for implementing National Environmental Policy Act (NEPA). Federal Register 51(186): 34190-34192.

Baker, K. F., and R. J. Cook. 1974. Biological Control of Plant Pathogens. W. H. Freeman & Co., San Francisco, 433 p.

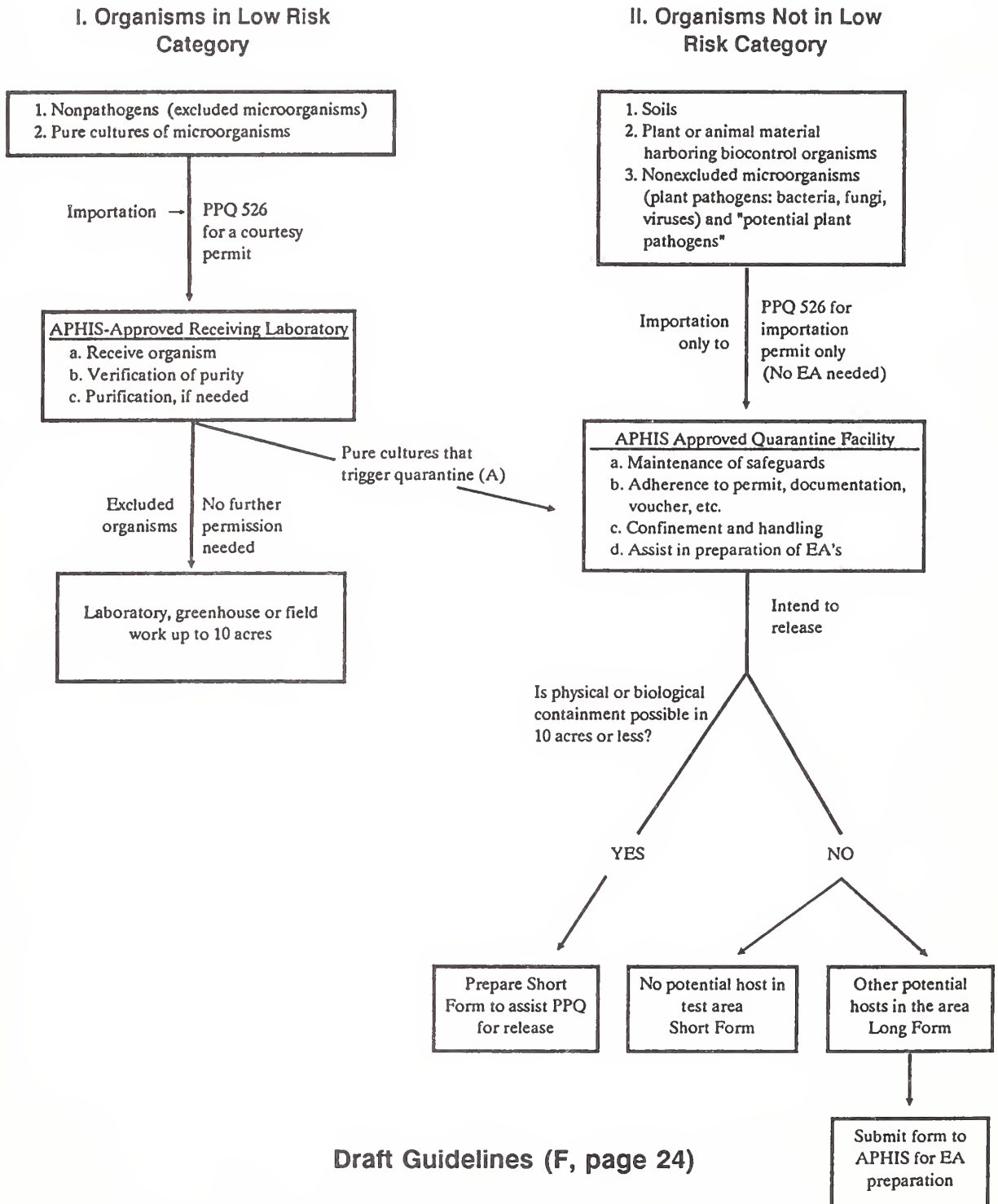
Cook, R. J., and K. F. Baker. 1983. The Nature and Practice of Biological Control of Plant Pathogens. Amer. Phytopathol. Soc., St. Paul, 539 p.

Coulson, J. R., and R. S. Soper. 1989. Protocols for the introduction of biological control agents in the U.S., p. 1-35 in Kahn, R. P. (ed.), Plant Protection and Quarantine, Vol. 3: Special Topics, CRC Press, Inc., Boca Raton, FL, 215 p.

Howarth, F. G. 1991. Environmental impacts of classical biological control. Ann. Rev. Entomol. 36: 485-509.

Lima, P. J. 1983. Safeguard Guidelines for Containment of Plant Pests Under Permit. U.S. Dept. Agr., APHIS 81-61, 13 p.

Biological Control Agents, Soils, Plant Materials



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PPQ Form 526: Application and Permit to Move Live Plant Pests or Noxious Weeds

SEE NO. 1 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

List of Plant Regulatory Officials of U.S. States and Territories, Canada, and Mexico

SEE NO. 3 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Draft AD Form 944: Record of Shipment of Exotic Microorganisms for Biological Control

SEE NO. 19 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

**Proposed List of Biological Control Agents for Plant Pathogens and Nematodes
Exempted from the Requirement of a Formal Environmental Assessment**

[LIST TO BE REFINED BY SCIENTIFIC PANEL IN ACCORDANCE WITH THE CRITERIA TO BE STATED ON ATTACHMENT 6.] The only pertinent organisms noted on previous draft lists as to be exempted are the following: (Elimination of those that are not pertinent to these Guidelines and addition of others proposed for exemption are needed.)

I. Bacteria:

1. *Agrobacterium radiobacter* K84-biovar 2
2. *Arthrobacter globiformis*
3. *Azotobacter chroococcum*
4. *Bdellovibrio bacteriovorus*
5. *Bradyrhizobium japonicum*
6. *Cellulomonas flavigena*
7. *Erwinia uredovora*
8. *Hafnia alvei*
9. *Pseudomonas fluorescens* - biovar 1,3
10. *Pseudomonas putida*
11. *Rhizobium japonicum*
12. *Streptomyces flavofungini*, *S. hygroscopicus*, *S. lavendulae*, *S. ochraciscleroticus*, *S. praecox*
13. *Xanthomonas maltophilia*

II. Fungi:

1. *Ambelomyces quisqualis*
2. *Arthrobotrys dactyloides*, *A. oligospora*
3. *Candelabrella javanica*, *C. musiformis*
4. *Catenaria auxiliaris*, *C. anguillulae*
5. *Chaetomium cochliodes*
6. *Coniothyrium minitans*
7. *Dactyella docdycoides*, *D. lobata*, *D. oviparasitica*, *D. spermatophaga*
8. *Dactylaria haptotyla*, *D. vermicola*
9. *Diheterspora chlamydosporia*
10. *Genicularia cytosporia*, *G. perpasta*, *G. paucispora*

III. Other microbial groups ???

IV. Predacious nematodes ???

V. Other invertebrates ???

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**Proposed Criteria for Exemption
of Biological Control Agents for Plant Pathogens and Nematodes
from the Requirement of a Formal Environmental Assessment**

[The following criteria for exemption of microorganisms in general were developed at the EA Protocol Workshop at Beltsville, MD, in May 1989. **THESE NEED REFINEMENT BY SCIENTIFIC PANEL.** Similar criteria in ARS Guidelines for invertebrate and other organisms proposed for similar exemption may be helpful in development of these criteria.

All non-pathogens -- plant, insect, animal, human -- i.e., "excluded" organisms

If pathogenic, then consider:

- a. Ubiquity (not known to have hypervirulent strains)
- b. Host specificity
- c. Occurrence of non-target effects
- d. Genetic stability and gene immobility
- e. Environmental persistence and reproductive potential
- f. Dispersion capability"

Using these general factors, a more specific criteria is required for listing specific groups of individual microbial organisms as exempted from an EA requirement. The criteria to be developed for use of the short form protocol document for providing information for an EA (Attachment 9) may also be helpful.]

[THIS DOCUMENT NEEDS REVIEW BY SCIENTIFIC PANEL AS TO WHETHER ALL ENTRIES ARE PERTINENT, AND/OR OTHERS ARE NEEDED.]

**Proposed Abbreviated Protocol Document
for Providing Data for Environmental Assessments
for Initial Field Release of Biological Control Agents
of Plant Pathogens and Nematodes in the United States
(Short Format)**

**Request for Environmental Evaluation
for Release of Potential Plant Pests**

Please provide information that addresses the subjects listed below. This information is needed to determine plant pest risk and impact on the environment for any request to release non-exempted microbial organisms into the environment from PPQ-approved quarantine or other containment facilities for the purpose of biological control of plant pathogens and nematodes that meet certain criteria.

1. Purpose and need for release.
2. Alternatives (i.e. pesticides; no action) to the release.
3. Test organism.
 - a. Identification and taxonomy of organism to be released. Name(s) and affiliation(s) of identifiers.
 - b. Geographical distribution and ecological profile of organism where it was originally collected or isolated.
 - c. Host specificity of organism to be released, including effects non-target organisms, especially those considered beneficial or endangered.
 - d. Potential of organism for vectoring plant/animal pathogens.
 - e. Provision for exclusion of parasites, hyperparasites, extraneous pathogens, etc.
4. Target host or prey.
 - a. Distribution and economic impact, detrimental and beneficial.
 - b. Brief statement of life history and ecology, including environmental profile.

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5. Description of field experiment.
 - a. Number and location of release sites.
 - b. Form in which organisms are to be released.
 - c. Time and season of release(s).
 - d. Provisions for monitoring of release(s), including containment or removal provisions if problems arise.
6. General statement of environmental effects of release(s).
 - a. Affected environment -- specific elements should include, but are not limited to, plants, soil, water, air, wildlife, threatened and endangered species, livestock, and human populations.
 - b. Non-target effects: Does it attack an economic crop, beneficial species, or endangered species? Is it a potential nuisance to man or domestic animals?
 - c. Any unavoidable adverse effects of release?
 - d. Potential for dispersal of the released organism. Can it be contained in the field?
 - e. Mitigating circumstances.
 - f. Researcher's recommendation.
7. List prior USDA permits for this and similar organisms.
8. Pertinent references.

Proposed Detailed Protocol Document for Providing Data for Environmental Assessments for Initial Field Release in the United States of Biological Control Agents: Long Format

SEE NO. 11 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed Criteria for Biological Control Agents for Plant Pathogens and Nematodes Requiring an Only an Abbreviated Protocol Document for Providing Environmental Assessment Information (Short Format)

THESE CRITERIA FOR DETERMINING WHEN THE SHORT OR LONG FORMATS FOR PROVIDING ENVIRONMENTAL ASSESSMENT INFORMATION NEED TO BE DEVELOPED BY A PANEL OF PERTINENT MICROBIOLOGISTS; SIMILAR CRITERIA FOR ARTHROPOD OR OTHER NATURAL ENEMY GROUPS IN THE PERTINENT ARS GUIDELINES CAN PROVIDE HELP IN DEVELOPMENT OF THE CRITERIA NEEDED HERE.

List of States with Regulations Affecting the Introduction or Release of Biological Control Agents within their Boundaries

SEE NO. 13 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES
TO BE PREPARED

Draft AD Form 944A: Documentation of Release of Exotic Microorganisms for Biological Control

SEE NO. 20 OF LIST OF ATTACHMENTS COMMON TO TWO OR MORE GUIDELINES

Proposed ARS Repositories for Cultures of Microbial Biological Control Agents for Plant Pathogens and Nematodes

THIS ATTACHMENT NEEDS COMPLETION AFTER CONSIDERATION BY ARS
ADMINISTRATORS AND SCIENTISTS

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Attachments Common to Two or More Guidelines

	Page
No. 1 PPQ Form 526 ¹	2
No. 2 Proposed PPQ/ARS Form __	3
No. 3 APHIS list of state regulatory offices ¹	4
No. 4 VS Form 16-3 ²	5
No. 5 AD Form 941 ³	6
No. 6 Form ARS-748 ⁴	7
No. 7 Biological Control Advisory Committee (BCAC)	8
No. 8 Exempted Invertebrate Biological Control Agents	10
No. 9 Criteria for Exemption of Invertebrates	14
No. 10 Abbreviated EA Protocol Document for Invertebrates	15
No. 11 Detailed EA Protocol Document for Biological Control Agents	17
No. 12 Criteria for Selecting Appropriate EA Protocol Document for Invertebrates	20
No. 13 State regulations affecting biological control (<i>to be prepared</i>)	21
No. 14 AD Form 942 ³	22
No. 15 AD Form 943 ³	23
No. 16 U.S. National Voucher Collection for Introduced Beneficial Arthropods	24
No. 17 TAG on Introduction of Biocontrol Agents of Weeds (TAGIBCAW), Charter	31
No. 18 Importation of Exotic Natural Enemies of Weeds from Canada	35
No. 19 Draft AD Form 944 ³	40
No. 20 Draft AD Form 944A ³	41

¹ Supplies of this form and of the complete list are available from APHIS, PPQ, BATS.

² Supplies of this form are available from APHIS, VS.

³ Supplies of these forms with instructions are available from ARS, BCDC.

⁴ Supplies of this form and instructions (Form ARS-748A) are available from ARS, SEL.

Number 1 of Common Attachments

No permit can be issued to move live plant pests or noxious weeds until an application is received (7 CFR 330 (live plant pests) or 7 CFR 360 (noxious weeds))

See reverse side for additional information

FORM APPROVED
OMB NO. 0579-0054

U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE PLANT PROTECTION AND QUARANTINE BIOLOGICAL ASSESSMENT AND TAXONOMIC SUPPORT HYATTSVILLE, MARYLAND 20782 APPLICATION AND PERMIT TO MOVE LIVE PLANT PESTS AND NOXIOUS WEEDS		SECTION A - TO BE COMPLETED BY THE APPLICANT 1. NAME, TITLE, AND ADDRESS (Include Zip Code) 2. TELEPHONE NO. 				
3. TYPE OF PEST TO BE MOVED <input type="checkbox"/> Arthropods <input type="checkbox"/> Noxious Weeds <input type="checkbox"/> Pathogens <input type="checkbox"/> Other (Specify)						
A. SCIENTIFIC NAMES OF PESTS TO BE MOVED	B. CLASSIFICATION (Orders, Families, Races, or Strains)	C. LIFE STAGES IF APPLICABLE	D. NUMBER OF SPECIMENS OR UNITS	E. SHIPPED FROM (Country or State)	F. ARE PESTS ESTABLISHED IN U.S.	G. MAJOR HOST(S) OF THE PEST
4.						
5.						
6.						
7. WHAT HOST MATERIALS WILL ACCOMPANY WHICH PESTS (Indicate by line number)						
8. DESTINATION		9. PORT OF ARRIVAL		10. APPROXIMATE DATE OF ARRIVAL OR INTERSTATE MOVEMENT		
11. NO. OF SHIPMENTS	12. SUPPLIER		13. METHOD OF SHIPMENT <input type="checkbox"/> Air Mail <input type="checkbox"/> Air Freight <input type="checkbox"/> Baggage <input type="checkbox"/> Auto			
14. INTENDED USE (Be specific, attach outline of intended research)						
15. METHODS TO BE USED TO PREVENT PLANT PEST ESCAPE			16. METHOD OF FINAL DISPOSITION			
17. Applicant must be a resident of the U.S.A. I/We agree to comply with the safeguards printed on the reverse of this form, and understand that a permit may be subject to other conditions specified in Sections B and C.			SIGNATURE OF APPLICANT (Must be person named in item 1)		18. DATE	
SECTION B - TO BE COMPLETED BY STATE OFFICIAL						
19. RECOMMENDATION <input type="checkbox"/> Approve <input type="checkbox"/> Disapprove <input type="checkbox"/> Accept USDA Decision		20. CONDITIONS RECOMMENDED				
21. SIGNATURE		22. TITLE		STATE		23. DATE
SECTION C - TO BE COMPLETED BY FEDERAL OFFICIAL						
PERMIT						24. PERMIT NO.
(Permit not valid unless signed by an authorized official of the Animal and Plant Health Inspection Service)						
Under authority of the Federal Plant Pest Act of May 23, 1957 or the Federal Noxious Weed Act of 1974, permission is hereby granted to the applicant named above to move the pests described, except as deleted, subject to the conditions stated on, or attached to this application. (See standard conditions on reverse side).						
This permit does not authorize the introduction, importation, interstate movement, or release into the environment of any genetically engineered organisms or products						
25. SIGNATURE OF PLANT PROTECTION AND QUARANTINE OFFICIAL		26. DATE	27. LABELS ISSUED	28. VALID UNTIL	29. PEST CATEGORY	

PPQ FORM 526 Previous edition may be used
(OCT 88)

Draft Guidelines (Common Attachments, page 2)

DRAFT

U.S. Department of Agriculture Animal and Plant Health Inspection Service Plant Protection and Quarantine Hyattsville, Maryland 20782 APPLICATION AND PERMIT TO MOVE LIVING BENEFICIAL ORGANISMS				SECTION A - TO BE COMPLETED BY THE APPLICANT 1. Name, address and telephone no. of applicant (include zip code)			
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Instructions: For shipment of beneficial insects, nematodes, and other invertebrates, and entomopathogen material, i.e., all biological control organisms classified by PPQ as non-plant pests, submit one copy through appropriate receiving State regulatory official to the above address. Use additional sheets for additional remarks; retain copy of completed form for files.

Scientific Name(s) of Organisms to be Moved	Classification (Order, Family, Other)	Life Stages if Applicable	Number of Specimens or Units	Shipped from (Country or State)	Usual Host or Prey	Name of Plant or Arthropod Host & Other Material if any to Accompany Shipment (Living or Dead?)	Do Hosts or Plants Included Occur in U.S. Area of Destination?	
A	B	C	D	E	F	G	H	
							Yes	No
2.								
3.								
4.								
5. Total Number of Shipments			7. Port of Arrival and Quarantine Facility Receiving Shipment, if applicable			8. Final Destination		
6. Approximate Date of Shipment								
9. Method of Shipment <input type="checkbox"/> Airmail <input type="checkbox"/> Air Freight <input type="checkbox"/> Baggage <input type="checkbox"/> Auto <input type="checkbox"/> Other (explain):								
10. Intended Use (Laboratory, Field Study, Other)								
11. Methods to be Used to Prevent Escape of Organisms and any Included Pest Material								
12. Method of Final Disposition				13. Signature of Resident, Applicant or Agent			14. Date	

SECTION B. - TO BE COMPLETED BY STATE OFFICIAL AS APPROPRIATE			
15. Status <input type="checkbox"/> Approve <input type="checkbox"/> Accept USDA Decision <input type="checkbox"/> Disapprove		16. Conditions Recommended	
17. Signature	18. Title	19. State	19. Date

SECTION C - TO BE COMPLETED BY APHIS OFFICIALS AS APPROPRIATE			
PERMIT			
(Permit not valid unless signed by an authorized official of the Animal and Plant Health Inspection Service) Permission is hereby granted to the applicant named above to move the organisms described, except as deleted, subject to the conditions stated on, or attached to this application/permit. (See standard conditions on reverse side.)			
20. APHIS Permit No.			
21. Signature of APHIS official	22. Date	23. Labels Issued	24. Valid Until

PPQ Form _____

Draft Guidelines (Common Attachments, page 3)

Number 3 of Common Attachments

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE
HYATTSVILLE, MARYLAND 20782

September 1991

PLANT REGULATORY OFFICIALS OF THE STATES, CANADA, AND MEXICO
(Including: District of Columbia, Puerto Rico, Guam, Northern
Marianas Islands, Trust Territories, and the U.S. Virgin Islands)

Alabama: Guy W. Karr, Supervisor
Plant Industry Section
Department of Agriculture & Industries
State of Alabama
P.O. Box 3336
Montgomery, AL 36193
(Telephone: A/C 205, 242-2656)
PPQ.SPRO.MONTGOME.AL

Alaska: Frank Milke, Director
Division of Agriculture
Alaska Department of Natural Resources
P.O. Box 949
Palmer, AK 99645-D949
(Telephone: A/C 907, 745-7200)
PPQ.SPRO.PALMER.AK

American Samoa: Mataalii Fia, Director
Department of Agriculture
American Samoa Government
P.O. Box 366
Pago Pago, AS 96799
(Telephone: 3-2131)

Arizona: Keith Lakelly, Director
Arizona Commission of Agriculture and Horticulture
1688 West Adams, Room 421
Phoenix, AZ 85007
(Telephone: A/C 602, 542-4373)
PPQ.SPRO.PHOENIX.AZ

Arkansas: Don Alexander, Director
Division of Plant Industry
State Plant Board
P.O. Box 1069
Little Rock, AR 72203
(Telephone: A/C 501, 225-1598)
PPQ.SPRO.LITTLE ROCK.AR

FOR ADDITIONAL COPIES PLEASE CONTACT:

Andrea M. Elston, Program Specialist
ILMC, OD, R&D, APHIS, USDA
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6505 Belcrest Road
Hyattsville, Maryland 20782

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FTS: 436-4966

SprintMail: PPQMANUALS
FTU: RDOD

Distribution: SOL Regular

Draft Guidelines (Common Attachments, page 4)

Number 4 of Common Attachments

No controlled material, organisms or vectors may be imported or moved interstate unless the data requested on this form is furnished and certified. (9CFR 94.95 and 122)

U. S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES FEDERAL BUILDING HYATTSVILLE, MARYLAND 20782		FORM APPROVED - OMB NO. 0579-0006
APPLICATION FOR PERMIT TO: <input type="checkbox"/> IMPORT CONTROLLED MATERIAL <input type="checkbox"/> IMPORT OR TRANSPORT ORGANISMS OR VECTORS		1. MODE OF TRANSPORTATION
INSTRUCTIONS: Submit 2 copies to address above. Attach additional sheets, if necessary.		2. U.S. PORT(S) OF ENTRY
3. TO: (Name, address, and phone no. of applicant - include Zip Code)	4. FROM: (Name and address of shipper - include Zip Code)	
5. DESCRIPTION OF MATERIAL (Name of material, country of origin, animal source, etc.)		
6. QUANTITY OF MATERIAL TO BE IMPORTED AND FREQUENCY OF IMPORTATIONS		
7. PROPOSED USE OF MATERIAL, EXPECTED COMPLETION DATE, AND FINAL DISPOSITION TO BE MADE		
8. DESCRIPTION OF APPLICANT'S FACILITIES AND EQUIPMENT FOR HANDLING MATERIAL		
9. QUALIFICATIONS OF TECHNICAL PERSONNEL WHO WILL BE WORKING WITH THIS MATERIAL		
10. METHOD OF TREATMENT OF MATERIAL (Disease Safeguard)		
11. WORK OBJECTIVES, PROPOSED PLAN OF WORK AND ADDITIONAL PERTINENT INFORMATION		
12. PERTINENT PUBLISHED PAPER OR ABSTRACT (Please attach copy, if available)		CHECK IF COPY IS ATTACHED <input type="checkbox"/>
I certify this material will be used in accordance with all restrictions and precautions as may be specified in the permit.		
13. SIGNATURE OF APPLICANT	14. TYPED NAME OF OFFICIAL SIGNING	
15. DATE SIGNED	16. TYPED TITLE OF OFFICIAL SIGNING	

VS FORM 16-3
(AUG 76)

Draft Guidelines (Common Attachments, page 5)

Number 5 of Common Attachments

OMB NO 0518-0013 (EXP. 2/28/87)

U.S. Department of Agriculture

Biological Shipment Record — Foreign/Overseas Source

☐ To Quarantine Facilities in Contiguous U.S. ☐ To Locations Outside Contiguous U.S.

37. FINAL DETERMINATION Gen., sp., subsp., auth. a <input type="checkbox"/> M <input type="checkbox"/> NC b <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> c <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		38. VS <i>(see files)</i> a <input type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/>
---	--	---

Section I — REPORT OF MATERIAL SHIPPED (To be completed by Shipper)

1. FROM (Facility or Explorer) 5. NOS. & STAGES SHIPPED <i>(see codes)</i> [Est] <input type="checkbox"/> [Est] <input type="checkbox"/> [Est] <input type="checkbox"/>	2. ORGANISM SHIPPED A. Gen., sp., subsp., auth. <input type="checkbox"/> M B. Order: Family _____ C. Determined by (names & affiliations) _____ 6. DATES TRANSFORMED TO STAGES SHIPPED <i>(month, day, year)</i>	3. SHIPPER'S FILE NO 4. TYPE OF ORGANISM explain MI & OT in blk. 18 <input type="checkbox"/> Parasite <input type="checkbox"/> WFed feeder <input type="checkbox"/> Predator <input type="checkbox"/> Pollinator <input type="checkbox"/> Microbial <input type="checkbox"/> Other 7. MATING OBSERVED <input type="checkbox"/> Yes _____ % <input type="checkbox"/> No 8. HOST/PREY/PEST MATERIAL PRESENT <input type="checkbox"/> Beneficial with host/prey <input type="checkbox"/> Host/prey/pest only <input type="checkbox"/> None 11. COLLECTORS
9. DATES ORIGINALLY FIELD COLLECTED <i>(m,d,y)</i> [Est] <input type="checkbox"/> [Est] <input type="checkbox"/>	10. LOCATION Country & Province/State & nearest Town or physical feature TOTAL:	
<input type="checkbox"/> Shipped directly <input type="checkbox"/> Emerged in Lab 13. LAB CULTURED (F1+) A. Culture Facility <i>(use acronym)</i> —explain in blk. 10 [Yes] <input type="checkbox"/> [No] <input type="checkbox"/>	12. ORIGINAL HOST/PREY <i>(or other food sources)</i> <input type="checkbox"/> M A. Gen., sp., subsp., auth. _____ B. Order: Family _____ C. Determined by (name and affiliation) _____ D. Specimens retained <input type="checkbox"/> Yes <input type="checkbox"/> No E. Stage/part (code) of host/prey attacked	15. FOOD PLANT/ANIMAL OF HOST/PREY A. Field (at collection) B. Lab (when cultured)
16. SHIPPED TO	17. INTENDED TARGET HOST/PREY Gen., sp. <i>(if different from blk. 12)</i>	18. REMARKS
19. DATE SHIPPED <i>(m,d,y)</i>	20. REPRESENTATIVE SPECIMENS RETAINED <input type="checkbox"/> Yes <input type="checkbox"/> No number: _____	21. PACKING/HANDLING <input type="checkbox"/> Usual <input type="checkbox"/> Other <i>(explain in blk. 18)</i>
22. SHIPPED VIA	23. SCREENED OR PACKAGED BY	

Section II — REPORT OF MATERIAL RECEIVED IN QUARANTINE (Or in facility outside contiguous U.S.)

24. DATE OF RECEIPT <i>(m,d,y)</i>	25. DATE OPENED <i>(m,d,y)</i>	26. CONDITION RECEIVED A. Container B. Contents	27. RECEIVER'S FILE NO
28. RECEIPT AND EMERGENCE RECORD <i>(use codes)</i>			
A. Number and Stages Received (block 2) Host/Prey or Parasitized Hosts		B. No. & Stages of Individuals of each Species Emerged Enroute and in Quarantine <i>(alive and dead)</i>	
Beneficials	Host/Prey or Parasitized Hosts	• Hosts/Prey • Beneficials • Other • Dates of Emergence • Notes	
Alive Dead Alive or PH Intact Dead or Parasites Emerged			
[Est] <input type="checkbox"/> [Est] <input type="checkbox"/> [Est] <input type="checkbox"/> [Est] <input type="checkbox"/> [Est] <input type="checkbox"/>			
29. REMARKS			
30. REPORTED OR EXAMINED BY			

Section III — FINAL RECORD OF RECEIPT, EMERGENCE, AND DETERMINATION IN QUARANTINE (Or in facility outside contiguous U.S.)

A. Genus, Species, Subspecies, Author	B. Order: Family	C. Determined by (name, affiliation, & date)	D. Number (stage - use codes)	E. Specimens Retained numbers
31. BENEFICIAL SPECIES				
a	M		[Est] <input type="checkbox"/>	[Yes] <input type="checkbox"/>
b	M		[Est] <input type="checkbox"/>	[Yes] <input type="checkbox"/>
c	M		[Est] <input type="checkbox"/>	[Yes] <input type="checkbox"/>
32. OTHER SPECIES (including other beneficials)				
d	M NC		[Est] <input type="checkbox"/>	[Yes] <input type="checkbox"/>
e	<input type="checkbox"/> <input type="checkbox"/>		[Est] <input type="checkbox"/>	[Yes] <input type="checkbox"/>
f	<input type="checkbox"/> <input type="checkbox"/>		[Est] <input type="checkbox"/>	[Yes] <input type="checkbox"/>
33. ORIGINAL HOST/PREY (final determination)				
	<input type="checkbox"/> <input type="checkbox"/>		[Est] <input type="checkbox"/>	[Yes] <input type="checkbox"/>
34. REMARKS			35. RELEASED, SHIPPED, CONSIGNED <i>(enter file numbers)</i> a [Yes] <input type="checkbox"/> b [Yes] <input type="checkbox"/> c [Yes] <input type="checkbox"/>	36. FINAL REPORT BY A. Name _____ B. Date <i>(m,d,y)</i> _____

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE — PLANT SCIENCES INSTITUTE
SYSTEMATIC ENTOMOLOGY LABORATORY-TAXONOMIC SERVICES UNIT

IDENTIFICATION REQUEST

- NOTE: • Please type or print all information.
• Do not write in shaded areas.
• Give explanations where requested in "Remarks" section at bottom of form.
• Attach additional pages if (and only if) more space is needed.

TSU LOT NO.	TSU PRIORITY
DATE	Sender's Reference No.
DATE IDENTIFICATION REQUIRED (month/day/year) If less than two months, explain below	
TOTAL NUMBER SENT Pinned Vials Stakes	Other:

NAME & COMPLETE MAILING ADDRESS OF SENDER (include Zip Code)

RETURN TO (if other than sender) (include Zip Code)

SOURCE

- | | |
|---|---|
| AR <input type="checkbox"/> ARS | SU <input type="checkbox"/> State University |
| AP <input type="checkbox"/> APHIS-PPQ | OS <input type="checkbox"/> Other State |
| FS <input type="checkbox"/> FS | PU <input type="checkbox"/> Private University |
| DD <input type="checkbox"/> U.S. Military | IN <input type="checkbox"/> Individual |
| OF <input type="checkbox"/> Other Federal | CO <input type="checkbox"/> Commercial Organization |
| SA <input type="checkbox"/> State Agricultural Agency | FN <input type="checkbox"/> Non-U.S. |
| | CI <input type="checkbox"/> CICP |

LEVEL/TYPE OF IDENTIFICATION NEEDED

☐ Family ☐ Genus ☐ Species☐ Positive or negative verification of ecological group:☐ phytophagous ☐ parasitic ☐ predaceous☐ saprophagous ☐ aphidophagous ☐ other:

OTHER INFORMATION REQUESTED—Will be supplied as conditions allow, as determined by taxonomist. Note reasons information is needed.

REASON FOR IDENTIFICATION (Check and complete as appropriate)

a ☐ Biological control1 ☐ Scientific name of target pest:2 ☐ General quarantine or biocontrol research3 ☐ Identity of host of natural enemy4 ☐ Recovery of released natural enemy5 ☐ Suspected contaminant in culture6 ☐ Quarantine reference collection7 ☐ Voucher specimen of field release8 ☐ Holding living material pending identificationb ☐ Damaging crop, plants—identify host plants:c ☐ Suspected pest of regulatory concern—give details belowd ☐ Stored product pest—commodity affected:e ☐ Livestock, wildlife, or domestic animal pest—host:f ☐ Danger to human healthg ☐ Household pest—damage:h ☐ Possible immigrant—new to:i ☐ Reference collection—for:j ☐ Survey—explain in detail belowk ☐ Thesis problem—describe project below ☐ M.S. ☐ Ph.D.l ☐ Other—explain below

SOURCE OF PROJECT SUPPORT

- | | | | | |
|--------------------------------|--|------------------------------|-------------------------------|------------------------------|
| <input type="checkbox"/> ARS | <input type="checkbox"/> APHIS | <input type="checkbox"/> FS | <input type="checkbox"/> CSRS | Regional project no: |
| <input type="checkbox"/> Hatch | <input type="checkbox"/> EPA | <input type="checkbox"/> DOI | <input type="checkbox"/> NIH | <input type="checkbox"/> NSF |
| <input type="checkbox"/> USAID | <input type="checkbox"/> Other (Specify) | | | <input type="checkbox"/> FAO |

SPECIMEN DISPOSITION—See Instruction Sheet. If you wish specimens returned, please provide justification below. Duplicate specimens encouraged—see instruction sheet.

☐ Return ☐ Keep or discard

TELEMAIL/ASRR or BITNET USER ID:

TELEPHONE REPORT REQUESTED
If yes, give number-include area code and extension.
Requests are handled at the discretion of SEL-TSU.

DESCRIPTION OF PROJECT—Include Project Title and name of Project Leader. (Reference previous communications pertaining to this submittal)

REMARKS (Explanations, tentative identification, etc.)

FOR TSU USE DATE RECEIVED
NO. LABELS SORTED PREPARED
DATE ACCEPTED
DATE OF RETURN

ARS-748 (9/88)

PART 1—SEL COPY

Draft Guidelines (Common Attachments, page 7)

**Proposed Structure and Procedures of the
Proposed BIOLOGICAL CONTROL ADVISORY COMMITTEE (BCAC)**

A mechanism for providing advice on issuance of permits for
importation and release of exotic beneficial organisms in the United States¹

The principal purpose of the advisory committee(s) (or advisory group) is to provide researchers and APHIS and other permit-granting authorities, upon request, with independent, broadly-based advice which takes into account all the potential risks and benefits associated with permit applications for importation and/or field release of exotic organisms in the United States. The following are some options for the structure of such advisory committees.

A. Number of Committees

(1) Establish a single general committee to deal with proposals ranging from microorganisms, genetically-modified organisms (GMOs), biological control organisms (including pathogens and invertebrates), pest invertebrates for research, to plants and animals.

(2) Establish two committees, (a) one dealing with GMOs and (b) the other dealing with all other proposals.

(3) Establish a number of more specialized committees which would allow a proposal to be considered by a group with expertise specifically related to the kind of organism being considered.

The Committee shown in the attached flow chart is in accordance with option 3.

B. Membership of BCAC

The BCAC would be limited to "experts," federal, state, and university scientists with expertise in botany, entomology, biological control, microbiology, ecology, genetics, etc., and include one or more members representing the general public and special interest groups (to assure that interests of the wider public are considered). The BCAC must have members who can assess the benefits of a proposal as well as its risks.

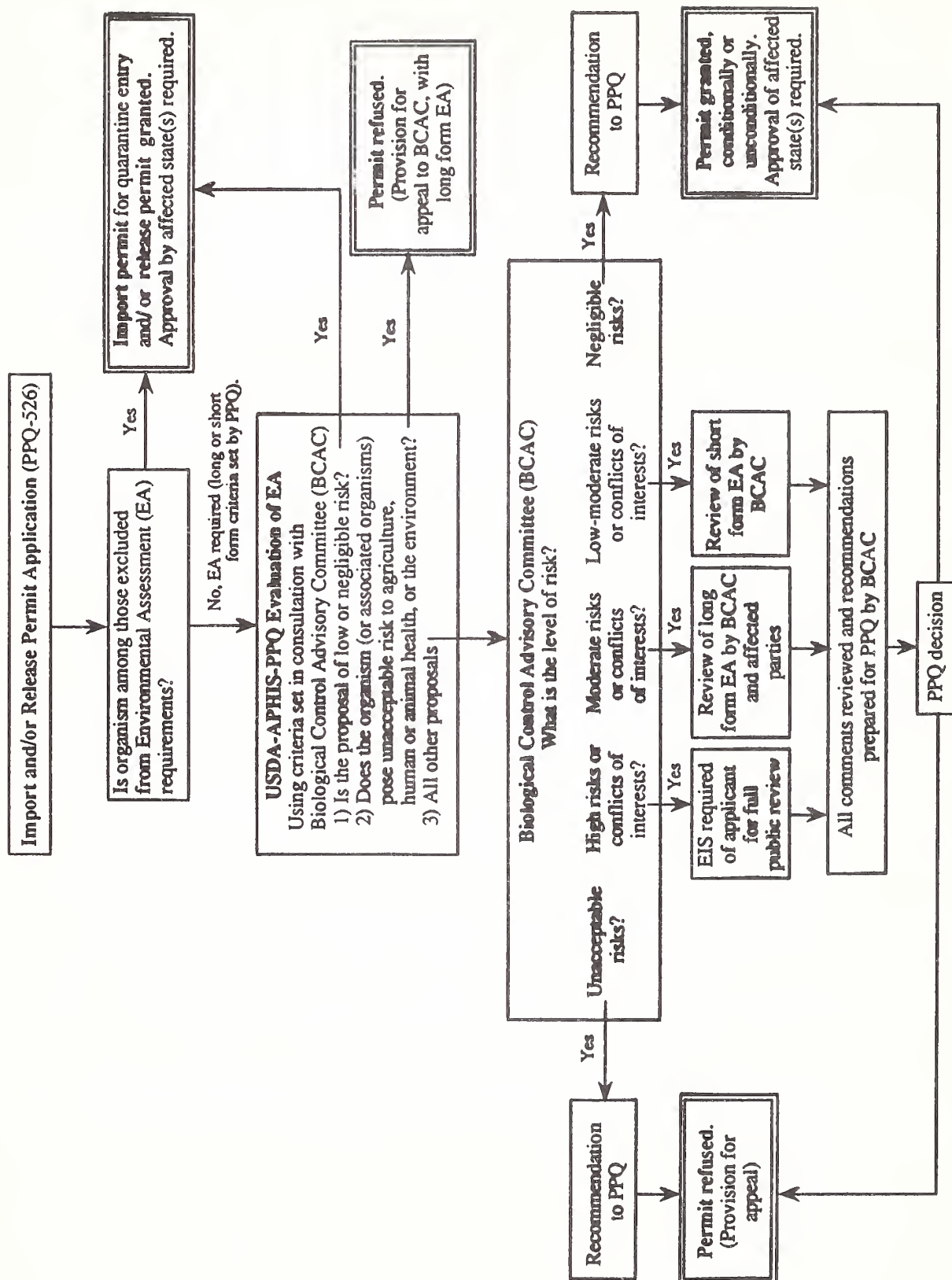
Committee membership could be static or vary with the proposal being considered. In the latter case, membership could be selected from a "pool" of previously-selected scientists, etc., with the option of co-opting other members as necessary for specific proposals.

C. Functions of the BCAC

(1) The first task of the BCAC on being established would be to develop the criteria which would be used to determine the level and nature of risk associated with each application and hence the degree of assessment, consultation, and level of containment that would be required. This pertains to the type and amount of data to be provided for an Environmental Assessment, as may be required by regulations under the National Environmental Policy Act (NEPA). APHIS, or other permit-granting authorities, would then apply these criteria in the initial assessment of each application received.

(2) In evaluating proposals submitted to it by APHIS, or other permit-granting authorities, the BCAC would provide advice and recommendations on (a) the level of risk (versus benefits) involved with the proposed importation or release, and (b) the degree and type of containment required for each type of organism approved for importation.

¹Revised from material in "New Organisms in New Zealand: A Discussion Document," New Zealand Ministry for the Environment, Wellington, 1988, 59 pp.



Draft Guidelines (Common Attachments, page 9)

**Proposed List of Invertebrate Biological Control Agents Exempted
from the Requirement of a Formal Environmental Assessment (EA)**

Kingdom Animalia

Phylum Nemata--species of the following listed genera; all others require an EA

Class Secernentia

Order Rhabditida

Family Steinernematidae

Steinernema (= *Neoaplectana*) - all species and races

Family Heterorhabditidae

Heterorhabditis - all species and races

NOTE: The following families of nematodes contain obligate parasites of insects, but host specificity is poorly known. It is suggested that the short format for providing information for an EA be used for species in these families:

Class Adenophorea

Order Enoplida

Mermithidae

Class Secernentia

Order Tylenchidae

Sphaerulariidae

Allantonematidae)

Entaphelenichidae

Phylum Arthropoda--species of the following listed orders, families,
subfamilies, tribes, or genera; all others require an EA

Class Insecta--as listed; all others require an EA

Order Neuroptera--all exempted

Order Heteroptera--as listed; all others require an EA

Family Anthracoridae

Family Nabidae

Family Pentatomidae (species of the subfamily Asopinae only; all
others require an EA)

Order Coleoptera--as listed; all others require an EA

Family Cantharidae

Family Carabidae (Exception: species in the tribe Harpalini require
an EA)

Family Cleridae

Family Coccinellidae (Exception: species of the subfamily
Epilachninae require an EA)

Draft Guidelines (Common Attachments, page 10)

- Family Histeridae (but see Guidelines regarding natural enemies of medical and veterinary pests)
- Family Lampyridae
- Family Scarabaeidae (species of the subfamilies Scarabaeinae, Geotropinae and Aphodiinae only; all others require an EA)
- Family Silphidae
- Family Staphylinidae (but see Guidelines regarding natural enemies of medical and veterinary pests)
- Order Diptera--as listed; all others require an EA
 - Family Acroceridae
 - Family Asilidae
 - Family Bombyliidae
 - Family Cecidomyiidae (species of the genus *Aphidoletes* only; all others require an EA)
 - Family Chamaemyiidae
 - Family Cryptochaetidae
 - Family Dolichopodidae
 - Family Nemestrinidae
 - Family Pipunculidae
 - Family Pyrgotidae
 - Family Scenopinidae
 - Family Syrphidae (species of the subfamily Syrphinae only; all others require an EA)
 - Family Tachinidae
- Order Hymenoptera--as listed; all others require an EA; see also Guidelines regarding species associated with dung or that are otherwise natural enemies of medical and veterinary pests
 - Family Ampulicidae
 - Family Aphelinidae
 - Family Aphidiidae
 - Family Bethyidae
 - Family Braconidae (Exception: species of the genus *Perilitus* require an EA)
 - Family Diapriidae
 - Family Dryinidae
 - Family Encyrtidae (as listed; all others require an EA)
 - Subfamily Encyrtinae
 - Tribe Aphycini
 - Tribe Comperiini
 - Tribe Copidosomatini (Exception: species of the genus *Coelopencyrtina* require an EA)
 - Tribe Discodini
 - Tribe Encyrtini
 - Tribe Habrolepidini

Draft Guidelines (Common Attachments, page 11)

- Tribe Ixodiphagini
- Tribe Miraini
- Tribe Neocladini
- Tribe Prionamasticini
- Tribe Pseudorhopini
- Tribe Psilophradini
- Tribe Trechnitini
- Subfamily Tetracneminae
- Family Eucharitidae
- Family Eucoilidae
- Family Eulophidae (as listed; all others require an EA)
 - Subfamily Eulophinae
 - Tribe Eulophini (Exception: species of the genus *Dimmockia* require an EA)
 - Tribe Euplectrini
 - Tribe Elachertini
- Family Evaniidae
- Family Gasteruptiidae
- Family Ibaliidae
- Order Hymenoptera (continued)
 - Family Ichneumonidae (Exceptions: species in the subfamilies Cryptinae, Diplazontinae, Gelinae, Mesochorinae, and of the genera *Itopectis* and *Theronia* of the subfamily Ephialtinae require an EA)
 - Family Mymaridae
 - Family Oryssidae (= Orussidae)
 - Family Pelecinidae
 - Family Platygasteridae
 - Family Proctotrupidae
 - Family Pteromalidae (as listed; all others require an EA)
 - Subfamily Cleonyminae (species of the tribe Cleonymini only; all others require an EA)
 - Subfamily Macromesinae
 - Subfamily Spalanginae
 - Subfamily Eunotinae
 - Family Scelionidae (Exception: species of the genus *Gryon* require an EA)
 - Family Scoliidae
 - Family Signiphoridae
 - Family Stephanidae
 - Family Tiphidae
 - Family Trichogrammatidae
- Class Arachnida, Subclass Acari (as listed; all others require an EA)
 - Order Acariformes (as listed; all others require an EA)

Draft Guidelines (Common Attachments, page 12)

Family Podapolipidae
Order Parasitiformes (as listed; all others require an EA)
Family Phytoseiidae

Rationale

The rationale for exemption (i.e., inclusion on the list), of the various taxa listed above involve biological, ecological, and historical precedents; reasons for exceptions or exclusions from the list primarily involve hyperparasitic tendencies (e.g., ichneumonid genus *Itopectis*), excessively broad host/prey ranges (e.g., Order Odonata), or presence of plant pests (e.g., subfamily Epilachninae in Coccinellidae) within the taxon. Details concerning the biology and other aspects of these taxa appear in the references below. See also the following Attachment 10 for criteria for exemption. No vertebrates or snails appear on the list because nearly all biological control agents known to have had adverse impacts upon the environment following their intentional introduction into a new territory involve these taxa.

Selected References

- Clausen, C. P. 1940. Entomophagous Insects, McGraw-Hill Book Co., Inc., New York, 688 pp.
- Clausen, C. P. (Ed.). 1978. Introduced parasites and predators of arthropod pests and weeds: A world review. U.S. Dept. Agr., Agric. Handb. 480, 551 pp.
- Coulson, J. R., A. Carrell, and D. L. Vincent (compilers). 1988. Releases of beneficial organisms in the United States and Territories - 1981. U.S. Dept. Agr., Misc. Publ. 1464, 324 pp.
- Coulson, J. R., and R. S. Soper. 1989. Protocols for the introduction of biological control agents in the U.S., pp. 1-35 In R. P. Kahn (ed.), Plant Protection and Quarantine, CRC Press, Boca Raton, FL, Vol. III.
- DeBach, P., and E. I. Schlinger (eds). 1964. Biological control of insect pests and weeds, Reinhold Publ. Corp., New York, 844 pp.
- Krombein, K. V., P. D. Hurd, D. R. Smith, and B. D. Burks. 1979. Catalog of Hymenoptera in America North of Mexico, Smithsonian Institution Press, Washington, DC, 3 vols.
- Laing, J. E., and J. Hamai. 1976. Biological control of insect pests and weeds by imported parasites, predators, and pathogens, pp. 685-743 In C. B. Huffaker and P. S. Messenger (eds.), Theory and Practice of Biological Control, Academic Press, New York.
- Luck, R. F. 1981. Parasitic insects introduced as biological control agents for arthropod pests, pp. 124-284, In D. Pimentel, (ed.), Handbook of Pest Management in Agriculture, CRC Press, Boca Raton, FL, Vol. II, 501 pp.
- Poinar, G. O. 1975. Entomogenous Nematodes, E. J. Brill, Leiden, 317 pp.
- Poinar, G. O. 1979. Nematodes for Biological Control of Insects, CRC Press, Boca Raton, FL, 277 pp.

Proposed Criteria
for Exemption of Invertebrate Biological Control Agents for Arthropod Pests
from the Requirement of a Formal Environmental Assessment for Field Release

1. No known plant pest in taxon listed.
2. Historic use of other biocontrol agents in the taxon listed are without adverse environmental impacts.
3. Systematics are known and therefore there is significant understanding of the taxon's basic biology, behavior, and ecology.
4. No significant detrimental effects of any species in listed taxon reported in the literature.
5. Not harmful to humans and livestock.
6. Limited host range:
 - a. Included species do not attack beneficial natural enemies, or such attack is insignificant.
 - b. Included species do not attack other beneficial organisms (e.g., honey bees, pollinators), or such attack is insignificant.
 - c. Included species does not further endanger species listed on Federal or State lists of endangered or threatened species.

**Proposed Abbreviated Protocol Document for Providing Data for
Environmental Assessments
for Initial Field Release in the United States
of Exotic Invertebrate Biological Control Agents of Arthropod Pests
(Short Format)**

**Request for Environmental Evaluation
for Release of Potential Plant Pests**

Please provide information that addresses the subjects listed below. This information is needed to determine plant pest risk and impact on the environment for any request to release non-exempted predaceous or arthropod-parasitic arthropods or nematodes into the environment from PPQ-approved quarantine or other containment facilities for the purpose of biological control of insects and mites, and for proposed release of arthropods and nematodes for biological control of weeds that meet certain criteria.

1. Purpose and need for release.
2. Alternatives (i.e., pesticides; no action) to the release.
3. Test organism.
 - a. Identification and taxonomy of organism to be released. Name(s) and affiliation(s) of identifiers.
 - b. Geographical distribution and ecological profile of organism where it was originally collected or isolated.
 - c. Host specificity of organism to be released, including effects non-target organisms, especially those considered beneficial or endangered.
 - d. Potential of organism for vectoring plant/animal pathogens.
 - e. Provision for exclusion of parasites, hyperparasites, pathogens, and inquilines.
4. Target host or prey.
 - a. Distribution and economic impact, detrimental and beneficial. Are there conflicts of interest?
 - b. Brief statement of life history and ecology, including environmental profile.

Draft Guidelines (Common Attachments, page 15)

5. Description of field experiment.
 - a. Number and locations of release sites.
 - b. Numbers of organisms to be released.
 - c. Time and season of release(s).
 - d. Provisions for monitoring of release(s), including containment or removal provisions if problems arise.
6. General statement of environmental effects of release(s).
 - a. Affected environment -- specific elements should include, but are not limited to, plants, soil, water, air, wildlife, threatened and endangered species, livestock, and human populations.
 - b. Non-target effects: Does it attack an economic crop, beneficial species, or endangered species? Is it a potential nuisance to man or domestic animals?
 - c. Any unavoidable adverse effects of release?
 - d. Potential for dispersal of the released organism. Can it be contained in the field?
 - e. Mitigating circumstances.
 - f. Researcher's recommendation.
7. List prior USDA permits for this and similar organisms.
8. Pertinent references.

**Proposed Detailed Protocol Document for Providing Data for
Environmental Assessments for Initial Field Release in the United States
of Exotic Biological Control Agents ¹
(Long Format)**

- I. Abstract
- II. Proposed Release
 - A. Objectives
 - B. Goals
 - C. Procedures
 - D. Summary of site characteristics
- III. Purpose and Need
 - A. Significance of action
 - 1. Problem
 - 2. Solution
 - B. Alternatives to proposed action
 - 1. No action
 - 2. Action
 - a. chemical
 - b. biological
 - c. cultural
 - C. Goals of the program
- IV. Description of Proposed Release Organism
 - A. Taxonomy
 - 1. Validation of identification
 - 2. Relatedness to other species in release area
 - B. Distribution
 - 1. Geographic
 - 2. Habitat
 - C. Ecology in native region
 - 1. Habitat
 - a. range
 - b. utilization
 - 2. Community interactions
 - 3. Population dynamics
 - D. Biological characteristics
 - 1. Life cycle
 - 2. Dispersal
 - 3. Survivability
 - a. abiotic
 - b. biotic

- E. Host range
 - 1. Within target family
 - 2. Adjacent families
- F. Non-target host organisms
 - 1. Major agricultural crops of release region
 - 2. Hosts affected by relatives of release organism
 - a. crop
 - b. non-crop

V. Description of Target Organism

- A. Taxonomy
 - 1. Confirmation
 - 2. Relatedness to other species in release area
- B. Distribution
 - 1. Geographic
 - 2. Habitat
 - 3. Agricultural relatedness
- C. Ecology
 - 1. Habitat
 - a. range
 - b. utilization
 - 2. Community interactions
 - 3. Population dynamics
- D. Biological characteristics
 - 1. Life cycle
 - 2. Dispersal
 - 3. Mortality factors
 - a. abiotic
 - b. biotic
 - (1) susceptibility to release organism
 - (2) predators
 - (3) parasites
 - (4) pathogens
 - (5) other

VI. Research in Support of Release

- A. Country of origin field investigations
- B. Containment experiments
 - 1. Laboratory
 - 2. Greenhouse
- C. Previous restricted field trials (releases) in U.S.

VII. Environmental Consequences of Proposed Release

- A. Site description
 - 1. Location
 - 2. Physical environment

- 3. Characteristics
 - a. human communities
 - b. animal communities
 - c. plant communities
 - B. Physical environmental risks
 - 1. Air
 - 2. Water
 - 3. Land
 - C. Human health risk
 - 1. Acute
 - 2. Chronic
 - D. Ecological impacts
 - 1. Wildlife
 - a. vertebrates
 - b. invertebrates
 - 2. Plants
 - 3. Endangered and threatened species
 - a. federal
 - b. state
 - 4. Domestic animals and livestock
 - 5. Pollinators
 - 6. other biological control agents
 - E. Potential for dispersal from the release area
 - F. Cumulative impacts
 - 1. Persistence
 - 2. Environmental stability
-
- VIII. Mitigative measures
 - IX. Monitoring
 - X. Acknowledgments
 - XI. Preparers, Consultants, and Reviewers
 - XII. Literature Cited
 - XIII. Tables and Figures
 - XIV. Appendices

¹ This is the draft "Proposal Format and Data Requirements Associated with a Request for Release of a Biological Control Organism from Quarantine" developed June, 1991, by APHIS-PPQ-BATS (M. H. Royer) and APHIS BBEP-EAD (O. P. Young).

**Proposed Criteria for Biological Control Agents
Requiring Either (1) an Abbreviated or (2) a Detailed Protocol Document
for Providing Environmental Assessment Information
(Short or Long Formats)**

Criteria for Species Requiring Only the Short Format

1. Candidate species is not in an exempted or excluded taxon, but biological studies indicate that it is always a primary parasite, and never a hyperparasite or phytophage.
2. Candidate species is polyphagous, known to attack hosts in more than 10 families.
3. Candidate species could "bite" or "sting" humans or domestic animals, but the likelihood of such action is small.
4. Candidate species possibly could be involved in a conflict of interest because it belongs to a genus containing species which:
 - a. Attack genera used for biological control of weeds.
 - b. Attack genera used for biological control of insects and mites.
 - c. Attack honeybees or other important pollinators.
 - d. Attack genera containing endangered species.

Criteria for Species Requiring the Long Format

NOTE: CANDIDATE SPECIES FITTING THREE OR MORE OF THE BELOW CRITERIA REQUIRE DEVELOPMENT OF AN ENVIRONMENTAL IMPACT STATEMENT.

1. Candidate species has hyperparasitic or cleptoparasitic tendencies (e.g., *Monodontomerus aereus* Walker released against gypsy moth in the early 1900's).
2. Candidate species is *highly* polyphagous, and known to attack hosts in several orders (e.g., mantid).
3. Candidate species *readily* "bites" or "stings" humans or domestic animals, and is likely to frequent habitat of same. (All social Hymenoptera should probably be in this category.)
4. Candidate species *probably* will be involved in a conflict of interest because it *is known to*:
 - a. Attack genera used in biological control of weeds.
 - b. Attack genera used in biological control of insect and mite pests.
 - c. Attack honeybees or other pollinators.
 - d. Attack genera containing endangered species.

**List of States with Regulations affecting the Introduction or Release
of Biological Control Agents within their Boundaries**

[AN ANNOTATED LIST IS TO BE PREPARED]

Draft Guidelines (Common Attachments, page 21)

Number 14 of Common Attachments

U.S. Department of Agriculture		OMB NO. 0518-0013 (EXP. 2/28/87)																	
BIOLOGICAL SHIPMENT RECORD – QUARANTINE FACILITY		45. FINAL DETERMINATION - Gen., sp., subsp., auth.																	
(Shipment/Consignment from Quarantine)		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; text-align: center;">M</td> <td style="width:50%; text-align: center;">NC</td> <td style="width:50%; text-align: center;">46. V.S. (see files)</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">a <input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">b <input type="checkbox"/></td> </tr> </table>		M	NC	46. V.S. (see files)	<input type="checkbox"/>	<input type="checkbox"/>	a <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	b <input type="checkbox"/>							
M	NC	46. V.S. (see files)																	
<input type="checkbox"/>	<input type="checkbox"/>	a <input type="checkbox"/>																	
<input type="checkbox"/>	<input type="checkbox"/>	b <input type="checkbox"/>																	
SECTION I – REPORT OF MATERIAL SHIPPED, CONSIGNED or RELEASED																			
1. FROM (Quarantine facility - name and address)		2. ORGANISM SHIPPED - A. Gen., sp., subsp., auth. <input checked="" type="checkbox"/> M																	
5 NOS. & STAGES SHIPPED (see codes)		3. QUARANTINE FILE NO.																	
<div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Est <input type="checkbox"/> Est <input type="checkbox"/> Est </div> <div> TOTAL: <input type="checkbox"/> Shipped directly <input type="checkbox"/> Emerged in Quarantine </div> </div>		4. TYPE OF ORGANISM explain M & OT in blk. 20 <input type="checkbox"/> Parasite <input type="checkbox"/> Weed feeder <input type="checkbox"/> Predator <input type="checkbox"/> Pollinator <input type="checkbox"/> Microbial <input type="checkbox"/> Other																	
9. OATES ORIGINALLY FIELD COLLECTED (m,d,y)		6. OATES TRANSFORMED TO STAGES SHIPPED (month, day, year)																	
10. LOCATION - Country & Province/State of Origin		7. MATING OBSERVED <input type="checkbox"/> Yes _____ % <input type="checkbox"/> No																	
11. ORIGINAL COLLECTORS (names & affiliations)		8. HOST / PREY / PEST MATERIAL PRESENT <input type="checkbox"/> Beneficial with host/prey <input type="checkbox"/> Host/prey/pest only <input type="checkbox"/> None																	
12. FOREIGN/OVERSEAS SOURCE FILE NOS.		13. ORIGINAL HOST/PREY - Gen., sp. (or other food source)																	
14. STAGE/PART OF HOST/PREY ATTACKED		15. ORIGINAL FOOD SOURCE OF HOST/PREY																	
16. LAB CULTURED (F ₁ +) <input type="checkbox"/> Overseas <input type="checkbox"/> No <input type="checkbox"/> In Quarantine (number of generations)		17. LAB HOST/PREY - Gen., sp. (if different from blk. 13)																	
18. INTENDED HOST/PREY - Gen., sp. (if different from blk. 13)		19. SHIPPED/CONSIGNEE TO																	
20. REMARKS		21. OATE shipped/consigned (m,d,y)																	
22. REPRESENTATIVE SPECIMENS RETAINED number:		23. PACKING/HANDLING <input type="checkbox"/> Usual <input type="checkbox"/> Other (explain in blk. 20)																	
24. SHIPPED VIA		25. SCREENED OR PACKAGED BY																	
SECTION II – REPORT OF RECEIPT AND INTENDED USE																			
26. OATE OF RECEIPT (m,d,y)		27. OATE OPENED (m,d,y)																	
28. CONDITION RECEIVED A. Container B. Contents		29. REPORTED OR EXAMINED BY																	
30. INVENTORY OF MATERIAL RECEIVED (use codes) A. Number and stages received (blk. 2) <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th colspan="2">Alive</th> <th colspan="2">Dead</th> <th colspan="2">Beneficials</th> <th colspan="2">Host/Prey</th> </tr> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>		Alive		Dead		Beneficials		Host/Prey										31. OTHER SPECIES INCLUDED OR EMERGED A. Order: Family and Genus, species, author, if known B. Determined by (name & affiliation) C. No. and Stages (use codes)	
Alive		Dead		Beneficials		Host/Prey													
32. REMARKS		33. SPECIMENS FROM SHIPMENT RETAINED BY RECEIVER <input type="checkbox"/> Yes <input type="checkbox"/> No																	
34. INTENDED USE A. <input type="checkbox"/> Immediate release (complete Sec. III) B. <input type="checkbox"/> Release intended C. <input type="checkbox"/> No release intended		35. INTENDED LAB HOST/PREY - Gen., sp.																	
SECTION III – REPORT OF RELEASE																			
36. Types of release		37. Locations (State, County, nearest Town or physical feature, map coordinates) (Use AD-942A for more details)																	
38. Number and stages released. (see codes)		39. Dates of release (m,d,y)																	
40. Target hosts/prey at release A. Primary - Genus, species B. Other - Genus, species C. Families		41. Food (plant/animal/other) of target host/prey at release.																	
42. Released by (Name & affiliation)		43. REMARKS (use AD-942A for more details)																	
44. REPORTED BY A. Name B. Date (m,d,y)		45. REPORTED BY A. Name B. Date (m,d,y)																	

Number 15 of Common Attachments

U.S. Department of Agriculture		OMB NO. 0518-0013 (EXP. 4/30/93)	
BIOLOGICAL SHIPMENT RECORD – NON-QUARANTINE		34. FINAL DETERMINATION - Gen., sp., subsp., auth. M NC a. <input type="checkbox"/> <input type="checkbox"/> b. <input type="checkbox"/> <input type="checkbox"/>	
SECTION I – REPORT OF MATERIAL RELEASED OR SHIPPED			
1. FROM (Name & address of Shipper/Releaser)		2. BENEFICIAL - A. Gen., sp., subsp., auth. [M] B. Order: Family _____ C. Determined by (Name and affiliation if known) _____	
		3. SHIPPER/RELEASER FILE NO. (see instructions) 4. TYPE OF BENEFICIAL <input type="checkbox"/> Parasite <input type="checkbox"/> WEAd feeder <input type="checkbox"/> PRedator <input type="checkbox"/> POllinator <input type="checkbox"/> Microbial <input type="checkbox"/> Other (Explain M or OT): _____	
Part A. From U.S. Field Collection (Collected for field to field recolonization or laboratory culture) 5. COLLECTION LOCALITY(S) - State, County, nearest Town (If more than 2 collection sites, give State & County only)		And/Or Part B. From Laboratory Culture 9. SOURCE FILE NOS. <input type="checkbox"/> AD-942, AD-943: Nos. <input type="checkbox"/> Part A <input type="checkbox"/> Other: _____	
		10. COUNTRIES/REGION/STATE OF ORIGIN	
6. DATES OF COLLECTION (m,d,y)	7. COLLECTORS (Names and affiliations)	11. ORIGINAL COLLECTORS (Names and affiliations)	12. NO. LAB GENERATIONS (At shipper/releaser location) <input type="checkbox"/> F ₁ - F ₁₀ <input type="checkbox"/> F ₃₁ + <input type="checkbox"/> F ₁₁ - F ₅₀
8. U.S. FIELD HOSTS/PREY AT COLLECTION A. Genus, species	B. Stage/part attacked (see codes)	13. LABORATORY HOST / PREY A. Genus, species	B. Stage/part attacked (see codes)
SECTION II – REPORT OF SHIPMENT			
14. SHIPPED TO (Name & address)		16. NO. & STAGES SHIPPED (use codes on reverse) [Est]	18. DATE SHIPPED (m,d,y)
VIA :		17. SHIPPER'S REMARKS	19. SPECIMENS RETAINED BY SHIPPER <input type="checkbox"/> No <input type="checkbox"/> Yes _____ nos.
19. DATE RECEIVED (m,d,y)	20. NO. & STAGES (use codes) A. Rec'd. Alive [Est] B. Emerged (Beneficials) [Est]	21. RECEIVER'S REMARKS	
22. SPECIMENS RETAINED BY RECEIVER <input type="checkbox"/> No <input type="checkbox"/> Yes _____ nos.	23. INTENDED USE A. <input type="checkbox"/> Immediate release (complete Sect. III) B. <input type="checkbox"/> Release Intended C. <input type="checkbox"/> No release Intended	24. INTENDED LAB HOST / PREY - Gen., sp.	
SECTION III – REPORT OF RELEASE/RECOLONIZATION (See instructions on coversheet; use Form AD-943A for more details)			
25. Types of release		SITE 1 <input type="checkbox"/> Field <input type="checkbox"/> Greenhouse <input type="checkbox"/> Cage <input type="checkbox"/> Other: _____ SITE 2 <input type="checkbox"/> Field <input type="checkbox"/> Greenhouse <input type="checkbox"/> Cage <input type="checkbox"/> Other: _____ SITE 3 <input type="checkbox"/> Field <input type="checkbox"/> Greenhouse <input type="checkbox"/> Cage <input type="checkbox"/> Other: _____	
26. Locations (State, County, nearest Town or physical feature, map coordinates) (Use AD-943A for more details; see instructions on coversheet)			
27. Number & stages released (Use codes; see instructions for recording multiple releases.)		[Est] [Est] [Est]	
28. Dates of releases (m,d,y) (See instructions for recording multiple releases.)			
29. Target hosts/prey at release A. Primary - Genus, species B. Other - Genus, species C. Families			
30. Food (plant/animal/other) of target host/prey at release			
31. Released by (Name and affiliation)			
32. REMARKS (Use AD-943A for more details)		33. REPORTED BY A. Name B. Date (m,d,y)	

Form AD-943 (5/90)

Part 1 - DOCUMENTATION CENTER COPY

Draft Guidelines (Common Attachments, page 23)

[THIS ATTACHMENT IS RETAINED PENDING DECISIONS AND ACTION BY ARS, AND FURTHER REVIEW BY BIOLOGICAL CONTROL COMMUNITY.]

**Proposed Structure of and Procedures for the U.S. National Voucher
Collection for Introduced Beneficial Arthropods**

Biological Control Documentation Center (BCDC)
Agricultural Research Service
U.S. Department of Agriculture

There is general agreement among most biologists that voucher specimens should be selected and preserved when organisms are used in scientific investigations and/or in applied programs involving beneficial organisms. In the past, biological control workers have often neglected consideration of the needs of taxonomists and of taxonomic collections during foreign exploration and natural enemy importation programs. They have in general neglected to take timely steps to select and preserve voucher specimens when live specimens or cultures of foreign beneficial arthropods and other invertebrates are obtained for study and/or release in a natural enemy importation program.

Failure to collect routinely such reference specimens at appropriate times in any program can lead to future confusion for taxonomists and other biologists concerning the identity of the organism(s) used in the program. This in turn can weaken the validity of research results and any future applications of such research. The structure and procedures outlined below are being established to help remedy this situation.

Some pertinent references concerning voucher collections including the National Voucher Collection for Introduced Beneficial Arthropods, include: Robinson, 1975; Yoshimoto, 1978; Knutson, 1978, 1980; and Lee et al., 1982.

I. Purpose of U.S. National Voucher Collection for Introduced Beneficial Arthropods.

The purpose of the U.S. National Voucher Collection is: To provide permanent reference specimens to substantiate the identity of any imported beneficial arthropod species released in the U.S. This will better enable all interested professionals to determine when and where a new species is released and/or established in the U.S., and will enable and encourage review and update of the identity of voucher specimens, and thus of the introduced arthropod species, as future taxonomic changes may require.

II. Definition of Voucher Sample for National Collection.

In biological control exploration and importation programs, there are several categories of voucher samples that would be useful. Some of these are listed below, with suggestions as to locations that would be appropriate for maintaining collections of such samples:

Draft Guidelines (Common Attachments, page 24)

- A. Original host/prey of exotic natural enemy - Invertebrates or plants (all stages as collected) from each major collection site; see B.
Maintain at overseas laboratory, or by foreign explorer, and/or receiving quarantine facility.
- B. Exotic natural enemy shipped from foreign locations - Invertebrates (all stages as collected):
From each major collection site (together with original host/prey).
From each original host/prey (together with original host/prey).
Maintain at overseas laboratory, or by foreign explorer, and/or receiving quarantine facility.
- C. Natural enemies shipped/consigned from quarantine - Invertebrates (all stages shipped, and other stages from lab culture).
Maintain at quarantine facility (and under some circumstances by National Voucher Collection).
- D. Natural enemies released in U.S. - Invertebrates (stages released, and other stages from lab culture).
Maintain by releaser (and under many circumstances by National Voucher Collection).
- E. Natural enemies recovered from releases in U.S. - Invertebrates (all stages as possible).
Maintain by recovering agency (and under many circumstances by National Voucher Collection).

In all cases, researchers should keep in mind the need to send specimens to major USDA and other taxonomic collections. (USDA agencies maintaining collections include the Systematic Entomology Laboratory (SEL), Beltsville, MD, for arthropods; the Nematology Laboratory, Beltsville, MD, for plant and entomogenous nematodes; the U.S. National Arboretum, Washington, DC, Foreign Disease - Weed Science Research Unit, Frederick, MD, and Systematic Botany and Mycology Laboratory, Beltsville, MD, for plant pathogens; and Insect Biocontrol Laboratory, Beltsville, MD, and Plant Protection Research Unit, Ithaca, NY, for entomopathogens).

For purposes of the U.S. National Voucher Collection for Introduced Beneficial Arthropods, the term "voucher sample" is defined as follows: The total complement of specimens preserved to represent the release in the U.S. of a foreign beneficial arthropod species from any separate country of origin or more specific major geographical area, into any given area of the U.S. and, if applicable, from any given original host/prey for use against any given U.S. target host/prey.

Emphasis of the BCDC voucher system will be on vouchering the first releases of such material. However, specimens representing additional releases of such material will also be included in the collections, as

Draft Guidelines (Common Attachments, page 25)

specimens become available, especially those from differing areas of original collection or from differing original hosts. Also, a separate voucher collection system will be maintained of specimens representing the first (and subsequent) recoveries of released material.

III. Size and Condition of Voucher Samples.

It is desirable for each voucher sample for the National Collection to contain adequate numbers of adult specimens representative of each sex and/or of each developmental life stage included in the release. It is recommended that each voucher sample contain a minimum of 12 adults when possible, and an optimum of 30 if pinned or pointed, and 100 if preserved in alcohol for subsequent slide preparation. This sample should include adults of both sexes or other specimens of the stage(s) released. If the species released is from a laboratory culture, and/or immature specimens of the species released are otherwise available, these should be sent and will be included in the national collection, referenced to the actual voucher specimens.

It is realized that an appropriate sample size may depend to some extent on the preparation requirements of the project or taxonomic group involved. It is suggested that well-preserved specimens resulting from incidental mortality be used whenever possible. Preparation and shipping instructions in Steyskal et al. (1986), should be followed.

IV. Data Required for Voucher Samples.

The completeness and accuracy of data that are recorded along with any specimen greatly increases the usefulness of that specimen. Therefore, the following data will be requested to be included with any voucher sample submitted to the U.S. National Voucher Collection:

- A. Origin data: Place and date of collection, name and affiliation of collector, name of original host or prey of the specimens or of the parent generation if the specimens have been laboratory cultured. If the voucher sample can be associated with any specific foreign shipment record(s), the foreign shipment file number(s) (from AD Form 941 or other shipment records) should also be included. As noted above, voucher samples of the original host/prey or of the parent generation of the beneficial species under culture, should be maintained by the foreign and/or quarantine facility as appropriate.
- B. Release data: Place and date of release of the material which the voucher sample represents, name and affiliation of releaser, intended host/prey, quarantine file number(s) and/or non-quarantine file number(s) as appropriate (from AD Forms 942 and 943, respectively, or other record forms). If the material is cultured at the releasing facility, the number of generations produced at that facility at the time of release should be included.
- C. Identification data: Species determination, name and affiliation of identifier, and date of determination.

Most of the origin and release data will be present on the AD 942 and AD 943 release/shipment forms, if used (see Section VI), and/or should be provided on voucher data forms by the releaser and/or quarantine

facility. The identification data will be obtained by BCDC once the specimens become vouchers, from the taxonomist most appropriate for the particular taxa involved.

V. Specimen labels.

Three separate labels will be placed on each voucher specimen. These will be 1) label of origin, 2) label of field release (*voucher label*), and 3) label of determination. At least the voucher label will be a bright distinctive color. Labels will be attached by BCDC.

- A. Label of origin: This label will be attached first and will list the following data: 1) Specific original collection locality, 2) scientific name of original host/prey, 3) date of collection, 4) name and affiliation of collector, and 5) shipment file numbers if applicable.
- B. Label of field release (*voucher label*): This label will be attached by BCDC and will bear the following data: 1) specific release site, 2) release date, 3) scientific name of intended host/prey, 4) name(s) and affiliation(s) of persons responsible for the release, 5) shipment/release file number(s), as applicable, and 6) generation number (P, F₁, etc.).
- C. Label of determination: This label will be attached by the appropriate SEL taxonomist (or collaborating taxonomist) to at least the first and last specimens in a homogeneous series, and will bear the following data: 1) scientific name (including author), 2) name and affiliation of the identifier, and 3) date of determination. At BCDC, identical labels will be attached to each remaining specimen in the series as indicated by the taxonomist.

VI. Procedures. [TO BE REVISED]

- A. At Point of Foreign Origin (see also Section II, A and B).

When a beneficial arthropod and its parasitized or otherwise associated host material is collected for importation into the U.S., representative specimens should be collected of each beneficial and its original host/prey from each major collection site. Optimally, all stages as collected should be included in each voucher sample(s) of the beneficial(s) and in the separate voucher samples of the associated host/prey material. If living material is shipped from a foreign U.S. laboratory or facility, it is recommended that the foreign facility retain an adequate number of representative specimens of the beneficial and all associated host/prey material.

If the living material is shipped or hand carried to a U.S. quarantine facility by a U.S. explorer, the receiving quarantine facility should retain representative specimens of the material as originally collected.

- B. At U.S. Quarantine Facility (see also Section II, A-C).

Draft Guidelines (Common Attachments, page 27)

1. Receiving foreign shipment into quarantine: When original field collected or cultured material of live foreign organisms is received in quarantine, it is recommended that samples of both beneficial and host/prey species be retained by the receiving quarantine facility; samples of the beneficials may be later requested by the BCDC.
2. Shipment from quarantine: When any exotic beneficial organism is removed from quarantine status and then shipped or otherwise transferred to a non-quarantine situation, the quarantine facility will retain all specimens (all stages as shipped) of the exotic beneficial species that may die prior to shipment or transfer. These specimens may be used as (additional) voucher specimens if the beneficial organism is later released. Also, the following or similar type documents will accompany the shipments from quarantine: a) an AD Form 942 (with appropriate sections completed by quarantine facility); b) a blank voucher data form; and c) a form letter, with instructions to be followed in case of field release. The form letter will generally request that samples of representative specimens (all stages as released) of the beneficial organism (and its host/prey) be retained by the releaser pending request from BCDC or the quarantine facility, and will provide instructions for preparation of the specimens. The form letter and a voucher data form will be provided by the BCDC to all U.S. biological control quarantine facilities.

C. At Releasing Facility (see also Section II, D and E).

1. Immediate field release: If the beneficial organism is immediately field released, releaser should select at the time of release an adequate number of representative specimens (all stages as released) to serve as vouchers of that release. Those specimens should be combined with any specimens (from the shipment or culture) that died prior to release. The voucher sample(s) should be prepared according to form letter instructions and sent to the sending quarantine facility, or Documentation Center (BCDC), together with the completed voucher data form, if and when requested. The AD Form 942 or other documentation form should be completed and returned within 10 days of the release(s) to the quarantine facility.
2. Cultured prior to release: If the beneficial organism is cultured before release, the releaser should select at the time of release an adequate number of representative specimens (all stages as available) of the beneficial organism to serve as vouchers of the first release from culture. The voucher sample(s) should be prepared according to form letter instructions and sent to the pertinent quarantine facility, and Documentation Center (BCDC), together with the completed voucher data form, upon request. An AD Form 943 or other documentation form should be completed to document the release and sent to the Documentation Center within 10 days of the release. Voucher specimens of the laboratory host/prey should be kept by the releaser.

For subsequent releases of material from the culture, releaser should prepare samples taken periodically from the culture and should retain those samples pending request for

them by the Documentation Center. The vouchering of subsequent releases may sometimes be inappropriate due to the magnitude of some release programs.

3. Recoveries: Specimens representing field recovery in the U.S. of the released species following the passage of at least one overwintering season, should be kept by the releasing/recovering location. These should be prepared according to form letter instructions and a portion sent to the Documentation Center.

D. At Documentation Center.

When BCDC receives a voucher sample, a label of origin and a label of release (voucher label) will be prepared and affixed to each specimen or vial of specimens. BCDC will then send the entire sample to the Taxonomic Services Unit, SEL, for distribution to the appropriate taxonomist. The taxonomist will determine the identity of each specimen and attach a determination label to at least the first and last specimens in the series. The entire voucher sample will then be returned to BCDC where labels identical to the determination labels will be attached to all specimens in the voucher sample. BCDC will apprise the pertinent quarantine and releasing facility of the determination(s). BCDC will retain some specimens and distribute the remainder to the responsible taxonomist or appropriate collaborating taxonomist, for deposit in the U.S. National Collection of Insects, and to the Canadian National Collection (see Section VII). The location of all specimens of each voucher sample will be monitored by and kept on file at BCDC, and will be published periodically (see Section VIII).

VII. Housing of specimens.

Approximately one-third of the labeled voucher sample will be housed with the appropriate SEL or USNM specialist and will be integrated into the U.S. National Collection of Insects at the U.S. National Museum of Natural History (USNM) at Washington, D.C., or at Beltsville, Maryland. If specialists from other than SEL or USNM are required for determination, a few representative specimens from the voucher sample may be retained by the identifier, if desired. Approximately one-third of the sample will be housed and curated at BCDC as the U.S. National Voucher Collection of Introduced Beneficial Arthropods, at Beltsville, Maryland. Approximately one-third of the sample will be sent for deposit in the Canadian National Collection (CNC) of the Biosystematics Research Centre, Ottawa, on a reciprocal exchange basis. BCDC may also return some determined and labeled voucher specimens to the pertinent quarantine or other research facility. All voucher specimens will be on permanent deposit at BCDC (as well as at the USNM and CNC), and will be available for study and loan, but not for exchange or transfer.

VIII. Publication and Computerization of Records.

Computerization of U.S. importation and release files is now an active project at BCDC, i.e., the ROBO database (see Coulson et al., 1988). The ROBO database system has been designed to accommodate voucher collection data. An annual publication has been developed to document all releases of biological

control agents in the United States. Information on the existence of and locations of voucher specimens is included in the ROBO database associated with this publication. A periodic (e.g., every 5-10 years) list of specimens in the U.S. National Voucher Collection will be published, showing any pertinent nomenclatural or taxonomic changes.

IX. Proposed Guidelines.

After thorough review by the scientific community, information on the creation,, purpose,, location, procedures, and other pertinent facts concerning the "U.S. National Voucher Collection for Introduced Beneficial Arthropods" will be published in several media, including ESA Bulletin, IPM Practitioner, IOBC Newsletters, CAB Biocontrol News and Information, and Entomophaga.

X. References Cited.

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**Charter for the Technical Advisory Group
on the Introduction of Biological Control Agents of Weeds
(1990 Revision)**

The Technical Advisory Group (TAG) on the Introduction of Biological Control Agents of Weeds will function under Plant Protection and Quarantine (PPQ), Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), and will provide recommendations to the Deputy Administrator for PPQ, APHIS. It will replace the Ad Hoc Working Group on Biological Control of Weeds which functioned under the Joint Weed Committees of USDA and the U.S. Department of the Interior (USDI).

Objectives

1. Review research proposals on biological control of weeds involving potential introduction of exotic organisms into the United States to ensure that all aspects of the safety of the potential introductions are considered in the research plan.
2. Provide guidelines for researchers that must be met before an organism is considered for entry into or approved for release from quarantine in the United States.
3. Review the documentation supporting proposals to release exotic organisms for biological control of weeds in the United States and to evaluate the adequacy of the data showing the safety of the proposed release.
4. Recommend actions to be considered by PPQ to release or not to release biological control organisms from quarantine.

Plan of Work

1. The Chairman of TAG will be elected from among the membership. An Executive Secretary who is a PPQ employee will be appointed by PPQ.
2. TAG will have an Executive Board consisting of the Chairman and one member each from the Agricultural Research Service, APHIS, Cooperative State Research Service, USDI, and Environmental Protection Agency. The Board will be appointed annually by the Chairman, will have the sole responsibility to enhance consensus with TAG, and will review and concur in all recommendations prior to their submission by the Chairman to the Deputy Administrator, PPQ.
3. TAG will review research proposals on biological control of weeds involving potential introduction of exotic organisms into the United States and, as may be requested, proposals involving introductions into Canada and Mexico. Review is to include:

Draft Guidelines (Common Attachments, page 31)

- a. Advice on potential conflicts of interest (i.e., whether or not plants targeted for study are universally regarded as "weeds") and on what type of evidence is needed to resolve a conflict if one does exist.
 - b. May recommend additional plants on which host specificity studies should be conducted.
4. As may be requested by PPQ, TAG will review documentation that supports a request to introduce a foreign organism into a PPQ approved quarantine facility for further research. If not accomplished under item 3, proposals for research on the exotic organism in quarantine will be reviewed. TAG may suggest additional requirements be met before it will recommend approval.
5. TAG will review and recommend action on all proposals for the release of exotic organisms from quarantine facilities for the biological control of weeds; evaluate the adequacy of the data showing the safety of the proposed release; and can also provide further advice to the researcher on the appropriateness of the release of the exotic organism.
6. Upon receipt of a report from the Chairman proposing a release and/or a PPQ Form 526 (Application and Permit to Move Live Plant Pests and Noxious Weeds) sent via PPQ, TAG will seek comments on the proposed release of the organism in North America from Canadian and Mexican scientists and from other scientists as appropriate.
7. In order to comply with the requirements of NEPA, each petition for release of a natural enemy of weeds must be subjected to an Environmental Assessment (EA) prior to issuance of an APHIS permit for release. It is the responsibility of APHIS to prepare the EA from the data provided in the petition.
8. TAG members should seek advice, as needed, of specialists on the taxonomy, biology, and ecology of the type of organisms being considered for importation and of appropriate biological control specialists.
9. TAG will generally conduct reviews by mail. An annual meeting will be called by the Chairman and will include research workers to help resolve important controversial issues relating to biological control of weeds in North America. If there is disagreement among members concerning a particular petition, the Chairman may call a meeting or telephone conference to try to arrive at a consensus. This meeting or conference may include outside specialists and the involved researcher as may be deemed helpful by the Chairman. If this procedure fails to produce a consensus, the Chairman is authorized to bring the case before the Executive Board for resolution.
10. TAG will develop recommendations and provide advice to PPQ-APHIS but is not authorized to represent any specific Agency in PPQ program matters. It is understood that the responsibility of APHIS is to prevent the introduction of plant and animal pests into the United States. However, TAG is to consider other environmental aspects for the benefit of the researcher. In the event that a conflict of interest exists that cannot be resolved, TAG will recommend to PPQ procedures for resolving the conflict.
11. Member responses to petitions and the Chairman's recommendation to APHIS must be in writing and copies sent to all TAG members, the petitioners and to the ARS Biological Control Documentation

Center.

Duties of the Chairman

1. Presides over meetings of TAG and the Executive Board.
2. Serves as an in-depth reviewer (assess reviewer comments).
3. Prepares and transmits recommendations to the Deputy Administrator of PPQ with a copy to the researcher and members of TAG.

Duties of the Executive Secretary

1. Receives all petitions for proposals.
2. Makes distribution to members.
3. Compiles comments and sends to the Chairman for recommendation to APHIS.
4. Keeps a checklist to ensure all responsibilities are accomplished.
5. Maintains a file system for TAG.

Membership

Representation will be solicited for a period of 3 years from the following Agencies by APHIS. These representatives will serve as the voting members. Appointments can be renewed, and replacements will be solicited as may be otherwise required.

1. U.S. Department of Agriculture (four members)

Animal & Plant Health Inspection Service, Plant Protection & Quarantine
Agricultural Research Service
Cooperative State Research Service
Forest Service, as recommended by the Chief of the Forest Service

2. U.S. Department of the Interior (four members)

Bureau of Land Management
Bureau of Reclamation
Fish and Wildlife Service
National Park Service

3. U.S. Environmental Protection Agency, Office of Pesticide Programs (one member)

Draft Guidelines (Common Attachments, page 33)

4. U.S. Army Corps of Engineers, Waterways Experiment Station (one member)
5. Weed Science Society of America (one non-Federal member appointed by the President)
6. National Plant Board (one member)
7. Member-at-Large (one member for 1 year selected by the members)

**Proposed Guidelines for
U.S. Importation of Exotic Natural Enemies of Weeds from Canada**

These Guidelines are to be followed by U.S. locations and agencies involved in the collection or other receipt of exotic natural enemies of weeds from Canada, as follows:

- A. Organisms of exotic origin in Canadian quarantine, not yet cleared for field release in North America. See page 2.
 - 1. Request for importation for quarantine study in U.S. See page 2.
 - 2. Request for field release in U.S. and Canada made simultaneously. See page 2.
- B. Organisms of exotic origin cleared by U.S. and Canada for release *in Canada only*. See page 3.
 - 1. Request for release of the organism in U.S. made within three years of clearance for release of the organism in Canada. See page 3.
 - 2. Request for release in U.S. after more than three years of clearance for release in Canada. See page 3.
- C. Organisms of exotic origin cleared by U.S., Canadian, and Mexican authorities for release in North America (i.e., in both U.S. and Canada), or already cleared for release in the U.S. subsequent to Canada release. See pages 4-6.
 - 1. Organisms to be received from Canada *quarantine*, with or without host plant material. See page 4.
 - 2. Organisms to be *field-collected* in Canada. See pages 5-6.
 - a. Organisms to be received in U.S. *without plant host* material. See page 5.
 - b. Organisms to be received in U.S. *with plant host* material. See page 6.

NOTE: An Environmental Assessment (EA) must be prepared by the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) for all *initial* field releases into the U.S. of exotic natural enemies of weeds prior to issuance of a permit for release, in order to meet the requirements of the National Environmental Policy Act (NEPA). Guidelines for providing information required for completing the EA are available from APHIS-Plant Protection and Quarantine (PPQ), Hyattsville, MD, or the Executive Secretary of the Technical Advisory Group for Biological Control of Weeds (TAG BCW).

Draft Guidelines (Common Attachments, page 35)

- A. Organisms of exotic origin in Canadian quarantine, not yet cleared for field release in North America.
1. Request for importation for quarantine study in U.S.
 - a. Submittal of petition for review by APHIS-PPQ's TAG BCW is required. Only a brief petition is needed, which can be based on original Canadian proposal and TAG approval, with information on the additional testing proposed.
 - b. Receipt for testing *in approved U.S. quarantine facility* required.
 - c. PPQ 526 permits required, based on TAG approval, and with pertinent State approval.
 - d. Identification, to species level if possible, of organism received in U.S. quarantine must be confirmed by USDA (Systematic Entomology Laboratory (SEL), Nematology Laboratory (NL), or Systematic Botany and Mycology Laboratory (SBML), Beltsville, MD) or other qualified taxonomist.
 - e. Completion of importation forms (AD-941) and retention of labeled voucher specimens by receiving U.S. facility is required. AD-941 form should include documentation of confirmed identification; copies of completed form should be sent to Canadian supplier of the material and to the ARS Biological Control Documentation Center, Beltsville, MD.
 - f. If testing is favorable, subsequent petition to TAG for field release of material in the U.S. is required.
 2. Request for field release in U.S. and Canada made simultaneously.
 - a. Submittal of petition is required for review by TAG BCW for clearance for release in North America, *to include seeking Mexican concurrence*.
 - b. If organism is approved for release by TAG BCW, follow procedures noted under Section C below.
- B. Organisms of exotic origin cleared by U.S. and Canada for release *in Canada only*.
1. Request for release of the organism in U.S. made within three years of clearance for release of the organism in Canada.
 - a. Brief petition to TAG BCW is required. The petition to TAG should be sufficiently detailed to provide any information on U.S. native, economic, and endangered plants tested,

especially if tests of these plants were not required for Canadian clearance. *Mexican clearance will be sought* by the TAG based on information submitted by the petitioner from the original petition for release in Canada, and subsequent information presented in the new petition.

2. Request for release in U.S. after more than three years of clearance for release in Canada.
 - a. Brief petition to TAG BCW is required for re-evaluation of the release, based on information from petitioner on status of the natural enemy in Canada since its release (if established) and/or other updated information as, for example, that indicated in B1 above. *Mexican clearance will be sought* by the TAG based on information submitted by the petitioner from the original petition for release in Canada, and on the new information received.
3. If organism is approved by TAG for release, follow procedures noted under Section C below.

C. Organisms of exotic origin cleared by U.S., Canadian, and Mexican authorities for release in North America (i.e., in both U.S. and Canada), or already cleared for release in U.S. subsequent to Canada release.

1. Organism to be received from Canada *quarantine*, with or without host plant material.
 - a. Only APHIS-PPQ permit(s), with approval(s) of pertinent State(s), is required; no further TAG BCW involvement needed. Please note the requirement, prior to issuance of permits, of an Environmental Assessment (EA) for all *initial* U.S. field releases of exotic species, as per the NOTE on page 1 of these Guidelines.
 - b. If material has been *in culture* in Canadian quarantine for at least one generation on plant material of North American origin, direct receipt by State non-quarantine facilities of material from Canada quarantine is permitted.
 - c. If material is of exotic origin, *not reared* in Canadian quarantine, receipt in *approved U.S. quarantine* facility is required.
 - d. In both cases, identification, to species level if possible, of organism received in U.S. facilities must be confirmed by USDA (SEL, NL, or SBML) or other qualified taxonomists, and all subsequent specimens received should be checked against an identified voucher.
 - e. Sample of material received in U.S. must be checked by qualified persons (in Canada or U.S.) for parasites and pathogens. Any host plant material received in the U.S. must be destroyed (autoclaved or burned).
 - f. Completion of importation forms (AD-941) and retention of labeled voucher specimens by receiving U.S. facility is required. AD-941 form should include documentation of confirmed identification; copies of completed form should be sent to Canadian supplier of the material

Draft Guidelines (Common Attachments, page 37)

and to the ARS Biological Control Documentation Center.

g. Upon field release of the material, U.S. quarantine or non-quarantine facilities should complete quarantine release form (AD-942) or non-quarantine release form (AD-943), with copies to the ARS Biological Control Documentation Center.

2. Organisms to be *field-collected* in Canada.

a. Organisms to be received in U.S. *without plant host* material.

(1) Direct receipt by U.S. non-quarantine facilities is permitted; receipt in U.S. quarantine not required.

(2) Only APHIS-PPQ permit(s), with approval(s) of pertinent State(s), is required; no further TAG BCW involvement needed, unless as may be requested by APHIS-PPQ. Please note the requirement, prior to issuance of permits, of an Environmental Assessment (EA) for all *initial* U.S. field releases of exotic species, as per the NOTE on page 1 of these Guidelines.

(3) U.S. facility or agency that is to collect or receive material must contact the Canadian research or other agency responsible for establishment of the organism to ascertain the location of *approved* collection sites and optimum collection dates.

(4) The U.S. collecting facility or agency is responsible for verification of the identification of the organisms collected prior to their field release in the U.S.; see procedure noted in C1d above.

(5) The U.S. collecting facility or agency is responsible for verification by competent persons that material is parasite- and pathogen-free, prior to field release of the material in the U.S.; see C1e above.

(6) The U.S. collecting facility or agency is required to complete an importation form (AD-941), to include documentation of the collection, the identification confirmation, and results of the parasite/pathogen testing, and should provide copies to the appropriate Canadian location or agency and the ARS Biological Control Documentation Center.

(7) Upon further shipment or field release of the Canadian material, the U.S. facility or agency is required to complete non-quarantine release forms (AD-943) and retain labeled voucher specimens.

b. Organisms to be field-collected in Canada and received *with plant host* material.

(1) If State receiving material *directly adjoins* Canadian Province where collections are to be made, follow procedures noted under Section C2a above.

Draft Guidelines (Common Attachments, page 38)

(2) If State receiving material *does not adjoin* the Canadian Province where collections are to be made, initial receipt of material in *U.S. approved quarantine facility* is required.

(3) Receiving U.S. quarantine facility is responsible for obtaining APHIS-PPQ permits, with pertinent State approval (and EA if pertinent) (see C2a(2) above), obtaining approvals from the appropriate Canadian location or agency (see C2a(3) above), and the verifications as noted in C2a(4) and (5) above. All plant material received is to be destroyed (autoclaved or burned).

(4) Receiving U.S. quarantine facility is required to complete an importation form (AD-941), to include documentation of the collection, the identification confirmation, and results of the parasite/pathogen testing, and should provide copies to the appropriate Canadian location or agency and the ARS Biological Control Documentation Center.

(5) Upon further shipment or field release of the Canadian material, the U.S. quarantine facility is required to prepare quarantine release forms (AD-942) and retain labeled voucher specimens.

(6) Non-quarantine facilities receiving the Canadian material from U.S. quarantine should complete the AD-942 forms, and retain any dead specimens as vouchers.

United States Department of Agriculture
Record of Shipment of Exotic Microorganisms for Biological Control

Section I - REPORT OF SHIPPER

1. Shipment File No. _____	2. From Name _____ Affiliation _____ Address _____
3. Microorganism Shipped (provide a list of strains or isolates being shipped, if applicable, in Remarks block or an appended list) A. Scientific name _____ B. Identified by: _____ C. Class, Order, Family _____ D. Common name _____	
4. Specimen identification No. _____	5. Date Sent _____
6. Condition Sent A. Pure Culture: <input type="checkbox"/> B. With host material: <input type="checkbox"/> C. Other (explain): <input type="checkbox"/> <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> 1. Freeze dried <input type="checkbox"/> 2. Liquid culture </div> <div> <input type="checkbox"/> 3. Solid culture <input type="checkbox"/> 4. Smear <input type="checkbox"/> 5. Other </div> <div> Host: _____ Life stage (or plant part) of host: _____ </div> </div>	
7. Host Group <input type="checkbox"/> A. Weed pathogen <input type="checkbox"/> C. Arthropod pathogen <input type="checkbox"/> B. Microbial antagonist <input type="checkbox"/> D. Nematode pathogen <input type="checkbox"/> E. Other _____	
8. Original Collection Data A. Date: _____ C. Original collector: _____ B. Original host: _____ D. Location of collection: _____	
9. Storage History (conditions / time) _____	
10. Special Identifying Characteristics: _____	
11. Purification Method, Date, Place, Isolator _____	12. Relevant References (1 or 2) _____
13. Culture History A. Medium or host used: _____ D. Specimen retained yes _____ no _____ B. Method of inoculation (if host): _____ C. Passages prior to shipment: _____	

Section II REPORT OF RECIPIENT

14. Received By:	Name: _____ Date: _____ Affiliation: _____ Address: _____
15. Accession No. _____	16. A. Final Identification: B. Identified by: _____ C. Date: _____
17. Intended Use <input type="checkbox"/> A. Lab study (No release intended) <input type="checkbox"/> B. Lab evaluation, eventual release probable <input type="checkbox"/> C. Release <input type="checkbox"/> D. Transfer (all or part) to another location	18. Culture Available: Contact yes _____ Name: _____ Affiliation: _____ no _____ Address: _____

Remarks: (by Shipper or Recipient) Shipper Comments

Recipient Comments

United States Department of Agriculture
**Documentation of Release of
 Exotic Microorganisms for Biological Control**

Section I. IDENTIFICATION OF EXOTIC MICROORGANISM					
1 Release File No _____	2 Name of Microorganism A. Scientific _____ B. Common _____ C. Location and Identification of voucher specimens _____				
3 Shipped By: Name _____ Affiliation _____ Address _____ Original AD-944 File No. _____					
4 Received By: Name _____ Affiliation _____ Address _____ Receiver's Accession No. _____					5 Date Received _____
Section II. RELEASE RECORDS					
6 A. Environmental Assessment as required by NEPA obtained. Date _____ Experimental Use Permit No. _____			7. Purpose: Experimental use only _____ For establishment or dispersal _____		
Site I	Site II	Site III			
8 Type of Release: <input type="checkbox"/> Field <input type="checkbox"/> Greenhouse <input type="checkbox"/> Cage <input type="checkbox"/> Other			<input type="checkbox"/> Field <input type="checkbox"/> Greenhouse <input type="checkbox"/> Cage <input type="checkbox"/> Other		
9 Method					
10. Location					
11. Date(s)					
12 Form of Pathogen Released					
13 Released By					
14 Target Organism(s)					
Remarks:					

Proposals, Problems, and Questions associated with or included in these Guidelines that need further review and consideration by ARS, APHIS, and/or EPA Offices, or by Scientific Panels

Summary Guidelines

1. It is *recommended to ARS* that this document be suitably revised for promulgation as an ARS Directive.
2. Document Title and Section I. Though this document has not been reviewed by ARS scientists involved in the importation and release of exotic insect pollinators, it is *suggested to ARS* that the procedures discussed in it could be made applicable to this research program, and that it could be revised (as indicated) and associated Guidelines be developed (see No. 3d below), following such a review.
3. Sections I and III. It is *suggested to ARS* that consideration be given to the development of Guidelines for the following types of organisms, as these may be included in ARS research programs:
 - a. Introduced invertebrates and other organisms for biological control of snails;
 - b. Introduced snails and other invertebrates (other than arthropods and nematodes) for biological control purposes;
 - c. Introduced plants for biological control (or other beneficial purposes in which field releases are intended) (NOTE: There are strict Federal guidelines already in existence for the importation and movement of plant materials into the United States, and there are ARS Guidelines for proposing and conducting foreign plant explorations; in addition, SEA-ARS Directive 610.5 (6/7/79) sets forth guidelines regarding the release of weedy or poisonous plants);
 - d. Introduced pollinators (NOTE: See No. 2 above); and
 - e. Introduced vertebrates for biological control (or other purposes in which field releases are intended) (NOTE: Such guidelines need to be developed in consultation with APHIS-VS and with the U.S. Fish and Wildlife Service, who has regulatory responsibility regarding these and also certain invertebrate organisms under, e.g., the Lacey Act of 1900, the Endangered Species Act of 1973, the President's Executive Order 11987 (Exotic Organisms) of 1977, and the

Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990; under the latter Act, a Protocol Committee of the Aquatic Nuisance Species Task Force has been formed and provided protocol recommendations in 1991; *ARS was not represented on that Committee and may need to be included in future deliberations in regard to these types of introductions*).

4. Section II.B. Provision for Memoranda of Agreement or Compliance Agreements are included *only* in some of the Guidelines, as noted in A, C, and E below, and such provisions *need to be considered and approved by both ARS and APHIS*.

A. Guidelines for Arthropod Natural Enemies and Competitors of Arthropods

1. Sections I (p. 5), II (p. 6), III (p. 10-11), and V (p. 26-28 & 33), and Attachment 8. The formation of an interagency scientific panel, herein tentatively called a *Biological Control Advisory Committee* (BCAC), is proposed in this and the other five Guidelines. The committee would not make regulatory decisions, but would be for the use of APHIS and other Federal and/or State regulatory agencies as may be needed, in regard to certain proposed importations and releases in which the involved regulatory agencies wish to seek further scientific input, primarily regarding environmental safety factors, in order to make a regulatory decision, and could serve to resolve any substantive disagreements between APHIS and permit applicants. The committee could also be used by ARS and other biological control research workers who wish further scientific input in order to make research decisions concerning the environmental safety of a proposed release. Suggestions are made in these Guidelines and pertinent Attachments concerning organization, membership, and operation of the proposed committee; *these need review and approval by both ARS and APHIS and perhaps other agencies*. For example, the proposed BCAC is very closely related to the proposed "Protocol Review Committee" that has been recommended by the Protocol Committee to the Task Force established under the Nonindigenous Aquatic Nuisance Prevention and Control Act (see Summary Guidelines, Item 3c). The judicious establishment of an advisory or review structure as suggested in these Guidelines may serve both functions and several others in regard to the introduction of exotic organisms into the United States.

2. Sections III (p. 10, 12) and V (p. 28), and Attachment 2. It is *proposed to APHIS* that a form similar to the currently used PPQ Form 526 or VS Form 16-3 be developed (by APHIS or ARS) for application for permits for introduction, interstate movement, or release of biological control organisms not deemed to be plant or animal pests by APHIS. Such a form would be for use only in cases in which there are no known animal or plant host/prey materials or contaminants to be included in shipments of the biological control agents.

3. Sections III (p. 12), IV (p. 16 & 18), and V (p. 23-24 & 33). As noted here and in the Summary Guidelines (see Item 4, above), it is *recommended to ARS and APHIS* that Memoranda of Agreements (MOA) or Compliance Agreements be developed in the process of obtaining approval for operation of ARS biological control Quarantine Facilities. These are proposed only for facilities involved in introduction of (1) exotic arthropods, the most motile of the biological control agents considered in these six ARS Guidelines, and (2) exotic pathogens for weed control, which are often perceived to present the most potential risk to U.S. agriculture and environment of all the other biological control agents considered in these Guidelines. Such agreements would be between the ARS facility, the pertinent State regulatory agency, the appropriate non-governmental institution, e.g., state university, and APHIS. Provisions to be included in MOAs or Compliance Agreements are noted in these Guidelines.

4. Sections III (p. 15) and IV (p. 20). It is recommended to APHIS-VS and ARS that methods of shipment of animal dung for the purpose of importing biological control agents be discussed, and a method satisfactory to both agencies be designed for safe introduction of the maximum number of viable agents.

5. Section V (p. 29-32) and Attachments 9-13. It is imperative that current questions over safe and legal *mechanisms for obtaining ARS and/or APHIS approvals*, as may be required, for the release of exotic biological control organisms *be resolved*, in order for ARS classical biological control research to continue effectively. Both ARS and APHIS regulatory offices indicate that specific permission, involving preparation of an Environmental Assessment (EA), will be required for the *initial* release of any exotic biological control agent in the United States. The biological control research community has recommended a list (Attachment 9) of taxonomic groups of

beneficial species that present little or no risk to the environment and that should thus be exempted from the requirement of an EA, and has proposed criteria (Attachment 10) for assigning taxa to such a list. Formats for providing data for preparation of EAs have also been proposed: a "short format" for providing data in cases in which it is deemed little risk is involved (Attachment 11) and a "long format" for providing more detailed data in other cases (Attachment 12), and an attempt has been made to provide criteria for determining which format would be appropriate (Attachment 13). *The latter, however, needs careful review by a scientific panel*, particularly if no exemptions from an EA requirement are to be made (see item (1) in following paragraph), in which case the criteria listed in Attachment 10 serve to determine "low risk organisms" and use of the "short format" protocol document, and Attachment 13 may or may not then be required.

Questions that need resolution are the following: (1) Though permits for initial U.S. releases of exotic agents by ARS scientists may be required in all cases, are biological control agents in certain taxonomic groups of organisms to be exempted from the requirement of an EA preparation? If not, can the current list of organisms proposed for such exemption (Attachment 9) then be utilized as a list of "Low Risk Organisms;" i.e., species of groups so listed that are proposed for release to require a minimum amount of data from the scientists involved (e.g., as in Attachment 11) for preparation of an EA, rather than unnecessarily detailed data (as in Attachment 12)? (2) If permits for initial release of a species are to be required in all cases, it is assumed that APHIS will continue to issue them, even in cases in which the species is deemed not to be a potential plant or animal pest. But, can an EA and a Finding of No Significant Impact (FONSI) be prepared by ARS, and the FONSI submitted with the permit application to APHIS, as has been done in the past, and as is proposed on page 31 of these Guidelines? (3) There is a question as to what constitutes an "initial release." In these Guidelines, this is assumed to be initial release of a *species*. In others, the question may be raised as to whether the proposed release of "strains" or "biotypes" of a species are involved in considering an "initial" release. (4) The question can also be asked as to when a permit is to be obtained or an EA prepared: when the organism is first proposed for removal from quarantine status, or when it is first proposed for field release. *Pertinent ARS and APHIS offices need further involvement in solving these*

problems, which severely impede future ARS classical biological control programs involving invertebrate organisms.

6. Section V (p. 30) and Attachment 14. It must be noted that the exemptions from tolerance noted in Attachment 14 are proposals made by EPA.

7. Section V (p. 36) and Attachment 18. The attached document has been carefully reviewed by taxonomists of the U.S. National Museum of Natural History, the ARS Systematic Entomology Laboratory, and Agriculture Canada's Biosystematic Research Centre. No action has been taken concerning the Collection since 1985, because of loss of personnel. A *decision by ARS* is needed as to whether the U.S. National Voucher Collection of Introduced Beneficial Arthropods is to be reinstituted, and supported.

8. Section VII (p. 37). A *decision by ARS and APHIS* is needed in regard to provisions noted here concerning shipment of live biological control organisms to other countries by ARS scientists.

B. Guidelines for Arthropod-Parasitic Nematodes

1. Sections I (p. 4), II (p. 5), III (p. 9-10), and V (p. 19 & 25), and Attachment 13. These sections refer to the proposed establishment of the interagency scientific panel (BCAC), as discussed in A.1 above.

2. Sections III (p. 9 & 11) and V (p. 21), and Attachment 2. These comments refer to the proposed new permit application form for beneficial organisms (non-plant pests), as discussed in A.2 above.

3. Section III (p. 9-10 & 13) and Attachment 3. The facility requirements for adequate containment of foreign arthropod-parasitic nematodes upon their initial receipt and during later research need *review by a panel of nematologists*, particularly regarding nematodes attacking potential vectors of human and animal diseases, and in regard to the ARS facilities meeting those requirements.

4. Section V (p. 22-24) and Attachments 8-12. These comments refer to the questions concerning exemptions, criteria, Environmental Assessments, and approvals

regarding initial release of a foreign biological control organism in the United States, as discussed in A.5 above.

5. Section V (p. 22-23) and Attachments 8-12. These Attachments need *review by a panel of nematologists* for the reasons noted on the Attachments following these Guidelines for nematodes.

6. Section VII (p. 28). These comments refer to the proposed provisions for export of live biological control organisms, as noted in A.8 above.

C. Guidelines for Invertebrate Natural Enemies of Weeds

1. Sections I (p. 4), II (p. 5), and VI (p. 23-29), and Attachment 14. These sections refer to the proposed establishment of the interagency scientific panel (i.e., the BCAC), as discussed in A.1 above. Some of these sections in these Guidelines provide comments to distinguish between the operation of the BCAC and the TAGIBCAW. Comments and proposals in these regards are also included in the paper presented in Appendix 2 of these Proceedings; *these need consideration by ARS and other biological control of weeds researchers and ARS and APHIS offices*.

2. Section IV (p. 13) and Attachment 6. Guidelines are proposed for the importation of biological control of weeds agents from Canada, including non-quarantine procedures, that *need review and approval by APHIS* and probably selected state regulatory offices. These Guidelines have been reviewed and approved by the TAGIBCAW.

3. Sections V (p. 15 & 17-18) and VI (p. 22 & 24). These sections refer to proposed Memoranda of Agreements or Compliance Agreements for ARS Quarantine Facilities, as discussed in A.3 above.

4. Section V (p. 17 & 20). The facility requirements for quarantine research on phytophagous nematodes for biological control of weeds, and any necessary associated procedures, needs *review by a panel of pertinent biological control of weeds scientists and nematologists*.

5. Sections VI (p. 25-26) and Attachments 10-12. These comments refer to the questions concerning procedures

for preparing Environmental Assessments and obtaining approvals for initial release of a foreign biological control organism in the United States, as discussed in A.5 above. Also, the "short format" protocol document (Attachment 10) and the criteria for its use (Attachment 12) need review by a *panel of biological control of weeds researchers and pertinent regulatory personnel*.

6. Section VI (p. 31) and Attachment 17. These refer to the U.S. National Voucher Collection of Introduced Beneficial Arthropods, as noted in A.7 above.

7. Section VII (p. 33). These comments refer to the proposed provisions for export of live biological control organisms, as noted in A.8 above.

D. Guidelines for Microbial Natural Enemies of Arthropods

1. Sections I (p. 4), II (p. 5), III (p. 10-11), and V (p. 21 & 24-26), and Attachment 13. These sections refer to the proposed establishment of the interagency scientific panel (i.e., the BCAC), as discussed in A.1 above.

2. Sections III (p. 10-12) and V (p. 21), and Attachment 2. These comments refer to the proposed new permit application form for beneficial organisms (non-plant pests), as discussed in A.2 above.

3. Sections III (p. 13), IV (p. 19), V (p. 22 & 26-28), and Attachments 5 and 15. These refer to the proposed use of two new documentation forms, AD-944 and AD-944A, currently being reviewed by the Office Of Management and Budget for finalization; the forms are expected to be printed and operational in 1992. These forms for use in documenting the importation and interstate shipment (AD-944) and field release (AD-944A) of *exotic* microbial organisms for biological control have been developed with the assistance of several insect and plant pathologists. Their use as described herein *may need further review by additional biological control microbiologists, and their use, as proposed, approved by ARS scientists and administration*.

4. Section V (p. 23-25) and Attachments 7-11. Many of the comments concerning obtaining approvals for initial (and subsequent) release of exotic biological control organisms as discussed in A.5 above are pertinent here.

However, approvals for release of *exotic microbial* organisms involve not only ARS and APHIS but also EPA, thus further complicating the procedures; approval of all three agencies is required for initial releases. Certain microbial organisms (Attachment 7) have been proposed to be exempted from the ARS and APHIS requirement of an EA for *initial* release in the field, though not from EPA's EUP requirement. The latter requirement poses some problems when the purpose of the release is to effect establishment of the organism in the United States, and in this respect differs from the purpose of field testing during the development of a microbial product; i.e., inoculative releases versus inundative releases, respectively (J. V. Maddox, 1991; reference cited in these Guidelines). *Problems in regard to EPA requirements for such inoculative releases still require resolution*, to permit the development of classical biological control research utilizing exotic microbial organisms in the United States. "Option 2" of the proposed procedures for obtaining approvals for initial field release of exotic pathogens for classical biological control purposes, as discussed on page 24, contains a suggestion that may begin to help resolve these problems; i.e., a provision for joint notification of both EPA and APHIS of proposed releases by an ARS office specifically responsible for approval of such releases by ARS scientists.

Problems also need to be resolved in regard to ARS and APHIS requirements for initial release of exotic microbial organisms for control of pest arthropods in the United States: a panel of research entomopathologists has recommended a list (Attachment 7) of taxonomic groups of beneficial species that present little or no risk to the environment and that should thus be exempted from the requirement of an EA; criteria for assigning taxa to such a list is required, as indicated in Attachment 8. Formats for providing data for preparation of EAs have also been proposed: a "short format" for providing data in cases in which it is deemed little risk is involved (Attachment 9) and a "long format" for providing more detailed data in other cases (Attachment 10); criteria for determining which format would be appropriate is needed, as indicated in Attachment 11). Attachments 7-11 need further review by a *scientific panel of entomopathologists and APHIS regulatory officials*.

Questions that need resolution are similar to those noted in A.5 above, and are as follows: (1) Though permits for initial U.S. releases of exotic agents by ARS scientists may

be required in all cases, are biological control agents in certain taxonomic groups of organisms to be exempted from the requirement of an EA preparation? If not, can the current list of organisms proposed for such exemption (Attachment 7) then be utilized as a list of "Low Risk Organisms;" species of groups so listed that are proposed for release to require a minimum amount of data from the scientists involved (e.g., as in Attachment 9) for preparation of an EA, rather than unnecessarily detailed data (as in Attachment 10)? (2) If permits for initial release of a species are to be required in all cases, it is assumed that APHIS will continue to issue them, even in cases in which the species is deemed not to be a potential plant or animal pest. But, can an EA and a Finding of No Significant Impact (FONSI) be prepared by ARS, and the FONSI submitted with the permit application to APHIS, as has been done in the past, and as is proposed on pages 24-25 of these Guidelines? (3) There is a question as to what constitutes an "initial release." The question may be raised as to whether the proposed release of "strains" or "biotypes" of a species are involved in considering an "initial" release. (4) The questions concerning EPA requirements for field study of exotic microbial organisms are discussed above. *ARS, APHIS, and EPA officials* need involvement in resolving these problems, which currently seriously hamper classical biological control utilizing pathogens of arthropod pests.

5. Section VI (p. 27) and Attachment 15. Currently, ARS repositories for cultures of arthropod bacteria, viruses, and fungi are located at facilities in Peoria, IL, Beltsville, MD, and Ithaca, NY, respectively. *ARS administration needs to determine* whether these and repositories for additional types of microbial cultures are to be adequately supported for optimal operation.

6. Section VI (p. 28). These comments refer to the proposed provisions for export of live biological control organisms for research purposes (not commercial preparations); see discussion in A.8 above.

E. Guidelines for Microbial Natural Enemies of Weeds

1. Sections I (p. 4), II (p. 5), V (p. 18, 20, & 22-24), and Attachment 9. These sections refer to the proposed establishment of the interagency scientific panel (i.e., the BCAC), as discussed in A.1 above. Some of these sections

in these Guidelines provide comments to distinguish between the operation of the BCAC and the TAGIBCAW. Comments and proposals in these regards are also included in the paper presented in Appendix 2 of these Proceedings; *these need consideration by ARS and other biological control of weeds researchers and ARS and APHIS offices.*

2. Section III (p. 11) and Attachment 5. These refer to draft guidelines proposed for importation of biological control agents of weeds from Canada, as discussed in C.2 above.

3. Sections III (p. 11), IV (p. 16), V (p. 24 & 26), and Attachments 6 and 10. These refer to the proposed shipment/release documentation forms and procedures, as discussed in D.3 above.

4. Sections IV (p. 12 & 14), and V (p. 17-18). These sections refer to proposed Memoranda of Agreements or Compliance Agreements for ARS Quarantine Facilities, as discussed in A.3 above.

5. Section IV (p. 12-13). The physical requirements for maximum containment for initial receipt and study of exotic plant pathogens for weed control need to be developed by *a panel of plant pathologists.*

6. Section V (p. 20-21) and Attachment 7. These proposals pertain to procedures for obtaining approval for initial (and subsequent) field release of exotic microbial weed control agents. Please refer to the comments in the first paragraph and items 2-3 of the third paragraph of D.4 above, all of which are pertinent to this subject. *ARS, APHIS, and EPA officials need to be involved in resolving these problems, which are currently severely impeding utilization of exotic plant pathogens for the biological control of exotic weeds.*

7. Section V (p. 25). Guidelines for proper preparation and storage of plant pathogen voucher material, and for a requirement dealing with the shipment and maintenance of such voucher material by ARS facilities, particularly those to be designated as repositories of such materials, need to be determined among *involved ARS plant pathologists and ARS administrative officials.* These involve such considerations as herbariums, spore collections, lyophilized cultures, lyophilized virus-infected tissue, and maintenance of other pure cultures.

8. Section VII (p. 26). These comments refer to the proposed provisions for export of live biological control organisms for research purposes (not commercial preparations); see discussion in A.8 above.

F. Guidelines for Natural Enemies and Antagonists of Plant Pathogens and Nematodes

1. Sections I (p. 5) and VI (p. 22). These refer to proposed provisions for export of live biological control organisms for research purposes (not commercial preparations); see discussion in A.8 and other paragraphs above regarding the various guidelines. These proposed provisions also need *further review by appropriate scientific panel*, as to whether they should also apply in regard to Guidelines for this particular group of biological control agents.

2. Sections I (p. 5), II (p. 6), and V (p. 20). These comments refer to the proposed establishment of an interagency scientific panel (i.e., the BCAC), as discussed in A.1 above, but which, as noted on p. 20, is not currently expected to play a role in regard to organisms involved in these Guidelines; there is a possibility of its use in the future, however.

3. Section II (p. 7-8). Certain safety considerations as noted here that concern exotic organisms involved in these Guidelines *need further review by an appropriate scientific panel* as to whether or not they are valid concerns.

4. Sections III (p. 9) and V (p. 17). These comments concern the possible use of a proposed PPQ/ARS Form entitled "Application and Permit to Move Living Beneficial Organisms" in cases in which non-plant pests are involved. The potential use of this proposed form is discussed in A.2 above and noted in other paragraphs above. The potential use of the form for organisms involved with these specific Guidelines *needs consideration by an appropriate scientific panel*.

5. Sections III (p. 11 & 15) and V (p. 21) and Attachments 4 and 11. These sections refer to documentation forms and procedures utilized for other microbial biological control organisms; see D.3 and E.3 above. The forms and proposed procedures *need consideration by a scientific panel and ARS offices*, as to their applicability for the organisms involved in these particular Guidelines.

6. Section V (p. 19-20) and Attachments 5-9. These comments refer to procedures for obtaining approval for initial field release of exotic organisms of the type covered by these Guidelines. These procedures have not presented the problems encountered in connection with other types of biological control organisms (see particularly D.4 above), since inoculative releases for establishment purposes is not generally the aim of such field studies for organisms involved in these Guidelines. However, the procedures suggested here need *review by ARS and APHIS officials, and an appropriate scientific panel*, the latter particularly in regard to the list of organisms proposed to be exempted from the requirement of an Environmental Assessment (EA) (Attachment 5) and the criteria for listing exempted organisms (Attachment 6); preliminary versions of these documents were prepared at an ARS EA Protocol Workshop in May 1989, and need further development, as indicated on the Attachments. See the comments in the second paragraph of A.5 above concerning "exemptions" versus "low risk organisms," and other questions posed in that paragraph.

Attachments 7 and 8 to these Guidelines, i.e., protocol documents for providing information for development of an EA, also need *review by the scientific panel*, and the criteria (Attachment 9) for determining whether the organism proposed for release requires an abbreviated or a detailed protocol document needs to be developed by the panel.

7. Section V (p. 22) and Attachment 12. Guidelines for proper preparation and storage of voucher material, and for a requirement dealing with the shipment and maintenance of such voucher material by ARS facilities, particularly those to be designated as repositories of such materials, need to be determined among *involved ARS microbiologists and ARS administrative officials*. These involve such considerations as spore collections, lyophilized cultures, lyophilized virus-infected tissue, and maintenance of other pure cultures. Voucher collection repository locations (SBML, BPDFL and elsewhere) and their adequate long term support also *need consideration by ARS administration*.

